
From: Sarika Patel [/O=FR/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C41998E197374F4286116AB30F0CB9AC-SARIKA N PATEL]
Sent: 8/2/2023 3:58:49 PM
To: Andrea Romero Pérez [Andrea.RomeroPerez@rws.com]; Andrea Turner [andrea.turner@rws.com]
CC: Elizabeth Daw [Elizabeth.Daw@rws.com]
Subject: FW: Fish & Richardson - IPR translation certification opportunity
Attachments: 2023-07-26-Sherman Declaration of Accuracy of Translation.docx; Ex. A to Sherman Declaration.pdf; Ex. B to Sherman Declaration-Revised Translation .pdf; Ex. C to Sherman Declaration.pdf

Hi Andrea,

For clarification, in addition to this new translation prepared by Mr. Benyunes, we would also like Mr. Sherman to sign the original updated declaration (attached), which does not require him to perform a new translation. Please let us know if Mr. Sherman has any proposed edits to this attached document or when we can expect a signed version.

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Sarika Patel
Sent: Wednesday, August 2, 2023 10:48 AM
To: 'Andrea Romero Pérez' <Andrea.RomeroPerez@rws.com>
Cc: Elizabeth Daw <Elizabeth.Daw@rws.com>; Andrea Turner <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Exhibit

12

Hi Andrea,

We would like to move forward with Mr. Benyunes performing this additional translation with one minor revision. Could he translate the entire paragraph in which the relevant sentence is located and not just the relevant sentence? Please let us know if there will be any changes in the cost to do so.

Thank you,

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Andrea Romero Pérez <Andrea.RomeroPerez@rws.com>
Sent: Monday, July 31, 2023 4:05 AM
To: Sarika Patel <patel@fr.com>
Cc: Elizabeth Daw <Elizabeth.Daw@rws.com>; Andrea Turner <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Hi Sarika,

Please see below the needed information –

Name: Stephen Benyunes
Native English speaker: Yes
German qualification: MITI professional qualification in German-English translation with a specialisation in chemistry.
Work history: He has 26 years' experience as a translator, 23 of which as specialist in pharmaceutical. He has worked with RWS since 1996.

Let me know if you need anything further.

Kind regards,
Andrea

Andrea Romero Pérez (*she/her*) | Deputy Manager - IP-Trans | **RWS Group**

RWS IP Services

Europa House, Chiltern Park, Chalfont St Peter, SL9 9FG, England

T: +44 (0)1753 480 200 www.rws.com

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From: Sarika Patel <patel@fr.com>

Sent: 28 July 2023 16:33

To: Andrea Romero Pérez <Andrea.RomeroPerez@rws.com>

Cc: Elizabeth Daw <Elizabeth.Daw@rws.com>; Andrea Turner <andrea.turner@rws.com>

Subject: RE: Fish & Richardson - IPR translation certification opportunity

Thank you Andrea,

Could you please provide us with the new translator's competency to provide the translation (e.g. native English speaker who studied German, years working as a translator and in what capacity, etc.)

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Andrea Romero Pérez <Andrea.RomeroPerez@rws.com>

Sent: Friday, July 28, 2023 10:08 AM

To: Sarika Patel <patel@fr.com>

Cc: Elizabeth Daw <Elizabeth.Daw@rws.com>; Andrea Turner <andrea.turner@rws.com>

Subject: RE: Fish & Richardson - IPR translation certification opportunity

Ili Sarika,

I can confirm that for us to provide you with a translation of the sentence in question* plus a signed declaration we would charge our minimum charge of **USD 160**.

*We believe this to be the sentence in question –

Die Anwendung ist einfach: Einmal täglich vor dem Stillen bzw. der Mahlzeit wird 1 Tropfen Vigantol® Öl vorne auf einem Löffel dem Baby zum Ablecken gegeben. Es darf nie direkt in

We could have this returned to you by close of business (UK time) 1st August as the translator would need to spend time looking at the context of the text and not just translating a sentence.

Additionally, I believe we may need a different declaration drawn up with the translator's correct details? Please let me know what information you need – please note we would not proceed with the request until the declaration has been drawn up and our translator has agreed to sign it.

Kind regards,
Andrea

Andrea Romero Pérez (*she/her*) | Deputy Manager - IP-Trans | **RWS Group**

RWS IP Services

Europa House, Chiltern Park, Chalfont St Peter, SL9 9FG, England

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From: Sarika Patel <patel@fr.com>

Sent: 28 July 2023 12:39

To: Andrea Romero Pérez Andrea.RomeroPerez@rws.com

Cc: Elizabeth Daw Elizabeth.Daw@rws.com; Andrea Turner andrea.turner@rws.com

Subject: Re: Fish & Richardson - IPR translation certification opportunity

Hi Andrea,

Thank you. Could you also please let me know if it is possible for a new translator to translate only the sentence that Mr. Sherman looked at containing the phrase zum ablecken? If so, how much would it cost for a new translator to translate just that sentence and how long would it take to get a signed declaration?

Thank you,

Sarika

On Jul 28, 2023, at 5:21 AM, Andrea Romero Pérez <Andrea.RomeroPerez@rws.com> wrote:

Dear Sarika,

Thank you for your request. I can confirm the following price for an **English** translation of the attached German document:

Chapter 15.9 on pages 256-261 only (PDF pages 40-45)

Filing rate: USD 575

Filing rate: The order will be assigned to a translator with the appropriate technical background. A second linguist will conduct an independent, rigorous proofread. Translations are suitable for filing or legal purposes or if certification is required.

Please note that we will need to look into our resources for this request before confirming a turnaround due to the nature of the declarations the translator may be asked to sign.

By submitting an order to RWS Group, you signify acceptance of our published Terms & Conditions of Business. Copies are available on request or can be found on our website at www.rws.com. We look forward to receiving your instruction.

Kind regards,
Andrea

Andrea Romero Pérez (*she/her*) | Deputy Manager - IP-Trans | **RWS Group**

RWS IP Services

Europa House, Chiltern Park, Chalfont St Peter, SL9 9FG, England

T: +44 (0)1753 480 200 www.rws.com

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From: Sarika Patel <patel@fr.com>
Sent: 27 July 2023 20:55
To: Andrea Turner <andrea.turner@rws.com>
Cc: Elizabeth Daw <Elizabeth.Daw@rws.com>; Andrea Romero Pérez <Andrea.RomeroPerez@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Hi Andrea,

How much would it cost to get another translation from a new translator?

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Andrea Turner <andrea.turner@rws.com>
Sent: Wednesday, July 26, 2023 8:30 AM
To: Sarika Patel <patel@fr.com>
Cc: Elizabeth Daw <Elizabeth.Daw@rws.com>; Andrea Romero Pérez <Andrea.RomeroPerez@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Dear Sarika,

I hope you are well. I have looped in my colleagues Liz and Andrea, who will support me in this matter going forward. Both are based in the UK and therefore an hour closer to your time zone than I am.

Regarding your questions below, David was Rebecca's supervisor in the past, and at the time of the first correspondence (2017) he was a Senior Translator. The reason David reviewed the original translation was that at the time, Rebecca was unavailable but the review could not wait. As Rebecca's supervisor and English native speaker, with qualifications in German, David had a phone call with Martina Tyreus Hufnagel and he was asked on the phone to review a certain passage as your colleagues believed RWS omitted some words from our translation. He subsequently signed the declaration.

David feels that due to his involvement he should not be re-translating the text. If you would like a new translation and certification, we will be happy to provide one – but it would need to be done by an independent translator (not David or Rebecca) and reviewed by an independent revisor. Please note that additional costs will apply for this service.

Please let me know how you would like to proceed.

Kind regards,
Andrea

Andrea Turner (*she/her*) | Key Account Manager | **RWS Group**
RWS IP Services
Waldburgstraße 21, 70563 Stuttgart, Germany
andrea.turner@rws.com | M: +44 (0)7795 537001 | www.rws.com
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From: Sarika Patel <patel@fr.com>
Sent: 25 July 2023 20:50
To: Andrea Turner <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity
Importance: High

Thank you Andrea. We would also like to know what David Sherman's relationship is to Amy Tinworth, the original translator. For example, was David Amy's supervisor at any time or a supervisor to her supervisor? Essentially, we would like to know why David reviewed Amy's original declaration and provided the correction relating to "licking" that he did to make her translation more accurate.

Please feel free to contact me if you have any questions or if you wish to discuss.

Thank you,

Sarika N Patel :: Fish & Richardson P.C. :: 817 374 2946

From: Andrea Turner <andrea.turner@rws.com>
Sent: Friday, July 21, 2023 8:53 AM
To: Sarika Patel <patel@fr.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Hi Sarika,

Thank you for the additional clarification. We think David's original declaration covered the last part - which German words correspond to the word "lick" and why we have agreed a translation should be inserted. We would therefore suggest you send over a draft of the new declaration so we can escalate and check this internally. As detailed below, David is a native English speaker who studied German. He has a BSc (Hons) in German from Aston University and an HNC in Mechanical Engineering. He has been working actively as a patent translator from 2009 to 2019. David is now the UK Head of Translation Operations. He oversees and works closely with our translators and has a wide range of experience.

Kind regards,
Andrea

Andrea Turner (*she/her*) | Key Account Manager | **RWS Group**
RWS IP Services
Waldburgstraße 21, 70563 Stuttgart, Germany
andrea.turner@rws.com | M: +44 (0)7795 537001 | www.rws.com
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From: Sarika Patel <patel@fr.com>
Sent: 21 July 2023 00:32
To: Andrea Turner <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Hi Andrea,

I have received additional instruction on what we are looking for. Instead of the below, the team would like Mr. Sherman to sign an updated declaration discussing his qualifications for translating, attesting to the accuracy of Ms. Tinsworth's translation if it is accurate, and explaining why he added the reference to "licking" to Ms. Tinsworth's translation. Basically, we want his declaration to clearly identify which German words correspond to the word "lick" in English and therefore make the inclusion of this word more accurate.

Please let me know if you have any questions. Happy to discuss this in more detail at any time tomorrow if needed.

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Sarika Patel

Sent: Thursday, July 20, 2023 10:18 AM

To: 'Andrea Turner' <andrea.turner@rws.com>

Subject: RE: Fish & Richardson - IPR translation certification opportunity

Hi Andrea,

Instead of having David verify that the translation of Amy Tinsworth is correct, we would like him to prepare a separate full translation of the Harder reference section 15.9, similar to what Amy did but this time performed by David. Essentially, we want David to be the declarant for his own translation instead of him approving someone else's translation. Is that possible? Or is there somebody else who can provide a new declaration and translation? We want the person who provides the declaration and translation to be the same person.

Please feel free to contact me with any questions. 817-374-2946

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Andrea Turner <andrea.turner@rws.com>

Sent: Thursday, July 20, 2023 9:57 AM

To: Sarika Patel <patel@fr.com>

Subject: Re: Fish & Richardson - IPR translation certification opportunity

Hi Sarina,

David is a native English speaker who studied German.

Could you clarify what you mean with a full translation of harder so I can clarify with David?

I'm about to go onto a plane so I won't be available again today.

Kind regards,
Andrea

Sent from my iPhone

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On 20 Jul 2023, at 14:37, Sarika Patel <patel@fr.com> wrote:

I am available to discuss at 10:30am or any time after 11:45am Central time if you would like to discuss our needs mentioned below.

Thank you!

Sarika

On Jul 20, 2023, at 8:02 AM, Sarika Patel <patel@fr.com> wrote:

Thank you Andrea,

I have a couple more questions before we can decide how to proceed. It David a native English speaker who studied German? We need to establish his qualifications for both languages.

Also, if David is not translating anymore, will he be able to provide us with a full translation of harder and not just verify Amy's translation? We may need a new certified translation to fix these issues.

If you could please let me know as soon as possible, I would appreciate it.

Thank you!

Sarika

On Jul 20, 2023, at 4:13 AM, Andrea Turner <andrea.turner@rws.com> wrote:

Good morning Sarika,

I have spoken to David this morning, his qualifications are as follows:

BSc (Hons) in German from Aston University and an IINC in Mechanical Engineering. He has been working actively as a patent translator from 2009 to 2019 –when he signed the original declaration he was still translating actively.

David is now the UK Head of Translation Operations and does not translate anymore. He oversees and works closely with our translators and has a wide range of experience.

He would be able to check the linguistic accuracy of Becky's translation and he has already checked that the addition of the term "to be licked off" was required (as per point 3 on the certificate).

Please let me know how you would like to proceed.

Kind regards,
Andrea

Andrea Turner (*she/her*) | Key Account Manager | **RWS Group**
RWS IP Services
Waldburgstraße 21, 70563 Stuttgart, Germany
andrea.turner@rws.com | M: +44 (0)7795 537001 |
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From: Sarika Patel
Sent: Wednesday, July 19, 2023 10:00 AM
To: 'Andrea Turner' <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Now works for me! could you please give me a call at 817-374-2946? Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214 292 4033

From: Andrea Turner <andrea.turner@rws.com>
Sent: Wednesday, July 19, 2023 9:44 AM
To: Sarika Patel <patel@fr.com>
Subject: RE: Fish & Richardson - IPR translation certification opportunity

Dear Sarika,

I hope you are well. I am currently on business travel but available for a call on my mobile phone now, unless you can detail the issue in an email?

Kind regards,
Andrea

Andrea Turner (*she/her*) | Key Account Manager | **RWS Group**

RWS IP Services
Waldburgstraße 21, 70563 Stuttgart, Germany
andrea.turner@rws.com | M: +44 (0)7795 537001 |
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<image001.png>

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From: Sarika Patel <patel@fr.com>
Sent: 18 July 2023 21:40
To: Andrea Turner <andrea.turner@rws.com>
Subject: FW: Fish & Richardson - IPR translation
certification opportunity
Importance: High

Hi Andrea,

We had some urgent issues come up with the
declaration prepared by Mr. Sherman. Are you and Mr.
Sherman available for a quick chat to discuss these
issues today?

Thank you,

Sarika N Patel :: Fish & Richardson P.C. :: 214
292 4033

From: Sarika Patel
Sent: Wednesday, February 15, 2023 11:54 AM
To: 'Andrea Turner' <andrea.turner@rws.com>
Subject: RE: Fish & Richardson - IPR translation
certification opportunity

Hi Andrea,

Thank you for reaching out. The reference that we need
a declaration of accuracy prepared for is Chapter 15.9 of
Wochenbettbetreuung in der Klinik und zu Hause
(Childbed care in clinic and at home). David Joshua
Sherman at RWS prepared this declaration for us in the
past, which I have attached to this email (see
attachment at page 1). We were wondering if Mr.
Sherman could prepare a similar declaration for us with
an updated date and signature, and if so, if you could
please provide us with a quote for this service.

Please feel free to contact me if you have any questions.
I am available for a call at any time on Friday 2/16
between 9:00a.m. and 7:00p.m. Central Time.

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 817
374 2946

From: Andrea Turner <andrea.turner@rws.com>
Sent: Wednesday, February 15, 2023 8:35 AM
To: Sarika Patel <patel@fr.com>
Subject: RE: Fish & Richardson - IPR translation
certification opportunity

[This email originated outside of F&R.]

Dear Sarika,

Many thanks for your email and enquiry, which has been forwarded to me. My name is Andrea Turner and I am the Key Account Manager for Fish & Richardson at RWS IP Services. I have been working very closely with the Fish & Richardson office in Munich for the last few years.

Could I please ask, do you have a reference/invoice number of the book we translated in 2017, and would you also be able to send a copy of the exhibit that requires translation and certification now? We would also appreciate if you could confirm the required language combination for the exhibit and your preferred deadline.

I will be happy to join you in a call, I have good availability tomorrow and Monday. If you let you know a date and time that is convenient for you, I will be happy to send a MS Teams invitation.

Kind regards,
Andrea

Andrea Turner | Key Account Manager | **RWS Group**
RWS IP Services
Waldburgstraße 21, Stuttgart, 70563, Germany
andrea.turner@rws.com | M: +44 (0)7795 537001 | [rws.com](https://www.rws.com)
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From: Sarika Patel <patel@fr.com>
Sent: 14 February 2023 17:21
To: David Sherman <David.Sherman@rws.com>
Subject: Fish & Richardson - IPR translation certification
opportunity

Hi David,

I am an attorney at Fish & Richardson P.C.. I am reaching out regarding your availability to certify a translation of a German Book that you translated for us in a prior matter in 2017. We now need a similar certification prepared for an exhibit in an IPR matter.

Please let me know if you are interested and time to briefly speak later this week.

Thank you!

Sarika N Patel :: Fish & Richardson P.C. :: 214
292 4033

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<Harder Book Ch 15.pdf>

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Reinhold W. Vieth et al.
U.S. Patent No.: 9,066,958 Attorney Docket No. 53953-0001IP1
Issue Date: June 30, 2015
Appl. Serial No.: 11/674,234
Filing Date: February 13, 2007
Title: VITAMIN D COMPOSITIONS AND METHOD OF
ADMINISTRATION TO A HUMAN BEING

SUPPLEMENTAL DECLARATION OF ACCURACY OF TRANSLATION

I, David Joshua SHERMAN, hereby declare as follows:

1. I attest that Exhibit B to this declaration is a true, full, and accurate translation of Section 15.9 of “Wochenbettbetreuung in der Klinik und zu Hause” [Childbed care in clinics and at home] (MOM-1006).

2. Rebecca Amy TINWORTH performed the attached translation from German into English of Section 15.9 of “Wochenbettbetreuung in der Klinik und zu Hause” [Childbed care in clinics and at home] (attached as Ex. A).

3. When Ms. TINWORTH prepared her translation of Section 15.9 of “Wochenbettbetreuung in der Klinik und zu Hause” (Ex. A), I was her supervisor. In that capacity, I know Rebecca Amy TINWORTH to be competent to perform this translation because she has a Bachelor of Arts (Honors) degree in German studies.

4. I have reviewed the translation prepared by Rebecca Amy TINWORTH in 2017, which I understand was submitted during the lawsuit *Ddrops, Inc. v. iHerb, Inc.*, No. 0:16-cv-04278 (D. Minn.). Except for one omission as I explain below, to

the best of my knowledge, this is a true and accurate translation of Section 15.9 of "Wochenbettbetreuung in der Klinik und zu Hause" (MOM-1006). Attached as Exhibit B are my minor revisions to Ms. TINWORTH's translation. I confirm that my addition of "to be licked off" as a translation for the German phrase "zum Ablecken" on page 4 of the translation in the fifth line of the second paragraph under Option 3 provides a fuller and more accurate reflection of the German text (MOM-1006). *See* Ex. B. This is because "zum Ablecken," which appears on page 21 of the German document (MOM-1006) translates directly to "for licking." The German word "ablecken" means "to lick off" in English.¹ Therefore, Ms. TINWORTH's English translation is true, full, and accurate with the inclusion of the phrase "to be licked off" as reflected in Exhibit B.

5. I am competent to attest to the accuracy of this translation, because I am a native English speaker and have a Bachelor's of Science degree in German from Aston University. I also have a Higher National Certificate in mechanical engineering. I have worked actively as a patent translator for ten years from 2009-2019. I am now the United Kingdom Head of Translation Operations at RWS IP Services, where I oversee and work closely with RWS's translators to confirm the accuracy of translations.

¹ CAMBRIDGE DICTIONARY, <https://dictionary.cambridge.org/dictionary/german-english/ablecken> (last visited Jul. 25, 2023) (webpage attached as Ex. C).

6. I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct; and further declare that I am aware that willful false statements and the like so made are punishable by fine or imprisonment, or both.

Dated: August 2, 2023

David Sherman
Head of Translation Operations
For and on behalf of RWS Group Ltd.
Europa House, Chiltern Park,
Chiltern Hill, Chalfont St. Peter,
Buckinghamshire,
United Kingdom

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Ddrops Company, Reinhold Vieth, and
Elaine Vieth,

Plaintiffs,

v.

iHerb, Inc. and Madre Labs, Inc.
d/b/a California Gold Nutrition,

Defendants.

Civil Action No. 0:16-cv-04278 (JNE-TNL)

DECLARATION OF TRANSLATOR

I, Rebecca Amy TINWORTH, hereby declare as follows:

1. I personally performed the attached translation from German into English of chapter 15.9 of "Wochenbettbetreuung in der Klinik und zu Hause" (also attached).
2. The attached translation is, to the best of my knowledge, a true, full and accurate translation of the attached German document.
3. I am competent to perform this translation, because I have a Bachelor of Arts (Honors) degree in German studies.
4. I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct; and further declare that I am aware that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code.

Dated: April 3, 2017



R. A. TINWORTH

For and on behalf of RWS Group Ltd
Europa House, Chiltern Park,
Chiltern Hill, Chalfont St Peter,
Buckinghamshire,
United Kingdom

MOM_0005956

15.9 Prophylaxis of bleeding, rickets and tooth decay

?	Why are babies given vitamin K drops?	p. 256
?	Do all babies need vitamin D tablets?	p. 257
?	Do newborn babies need to take daily fluoride tablets?	p. 260

? Why are babies given vitamin K drops?

Vitamin K is needed to help the blood to clot. Almost all newborn babies have sufficient stores of vitamin K in their bodies at birth to ensure that the blood will clot in the next few weeks of their life (breastmilk contains hardly any vitamin K, and intestinal bacteria in babies are not capable of synthesizing it themselves for the first few weeks after birth).

Vitamin K deficiency in babies aged between 1 and 12 weeks can lead to increased tendency to bleed.

This manifests itself in continued bleeding at the site of injection following the taking of a blood sample, in bleeding of the mucous membranes in the event of intubation or the insertion of a feeding tube, as well as in blood in the stools, bleeding of the umbilical cord or cerebral bleeding.

If a newborn baby is spitting-up blood in the first few days after birth, questions should be asked to clarify the most common causes of this phenomenon: in most cases, the baby will have swallowed blood from its mother, either during the birth (e.g. amniotic fluid containing blood, large episiotomy, Caesarean section) or through feeding from a bleeding nipple.

The connection between vitamin K deficiency and bleeding in infants was established 60 years ago and can occur in around 1% of children (Tönz 1990). As there is no way of knowing whether newborn babies have sufficient stores of vitamin K in their liver, prophylactic increase of vitamin K stores for at-risk children (e.g. following surgical delivery, premature birth or bleeding in children) has been recommended since the 1960s.

Dosage:

Since 1986, the German Association for Pediatrics' Committee on Nutrition advised that all neonates should be given a prophylactic dose of vitamin K following birth. Initially, a single intramuscular or subcutaneous injection of 1 mg of vitamin K was recommended prophylactically after birth. Following the establishment by a British study (Golding et al. 1992) of a connection between the intramuscular administration of vitamin K and an increase in the number of cases of childhood cancers, in 1992 the Committee amended its recommendation to three oral administrations, each containing a 1 mg dose of vitamin K. In

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1994, the Committee on Nutrition doubled the oral dose, due to more cases of bleeding as a result of vitamin K deficiency being observed once again.

Nowadays, nearly all neonates receive three doses of 2 mg of vitamin K orally.

Parents must be consulted beforehand and must agree to the prophylaxis. Babies will receive either 2 drops of **Kanavit®** drops or a 0.2 ml ampoule of **Konakion®** 2 mg directly into their mouths. The first dose is given by the midwife following birth (check-up 1), followed by two further doses by a pediatrician at medical check-ups 2 and 3. Each administration of vitamin K must be documented in the child's yellow medical check-up booklet.

Babies should not receive **the first dose of vitamin K** until they have had a lengthy feed at the breast. This is because, firstly, vitamin K is liposoluble and is better absorbed with colostrum, and secondly it gives neonates the chance to familiarize themselves with the taste of breastmilk before being confronted with the foreign taste of the drops (**Konakion®** tastes like the adhesive coating on a postage stamp).

Although no side effects have been described for the oral prophylaxis of vitamin K, the possibility that early contact with the ingredients contained in the solution may increase a child's disposition to allergies cannot be ruled out (**Konakion®** 2 mg contains: lecithin and glycocholic acid from soya beans, sodium hydroxide, hydrochloric acid, water, vitamin K1. **Kanavit®** drops contain: polysorbate, sorbic acid, water, vitamin K1). Where parents do not give their consent to the prophylaxis for this reason or for other reasons, all caregivers must accept this; in Germany, there is no obligation to take part in prophylaxes.

? Do all children need vitamin D tablets?

Many parents are uncomfortable with the idea of giving a healthy infant a tablet each day. This is understandable, given that tablets are usually prescribed to treat illnesses. The daily vitamin D tablet, by contrast, does not treat an illness, but is designed to prevent the possible occurrence of rickets. Parents need to be given accurate information on vitamin D and rickets by pediatricians, midwives and pediatric nurses so that they can make an informed decision with regard to a form of **rickets prophylaxis** (see below).

Children need **vitamin D** to store calcium, which in turn is needed to strengthen bones. Vitamin D also promotes the absorption of calcium and phosphate from the intestine. Infants produce their own vitamin D by converting provitamins in the skin to vitamin D under the effect of ultraviolet light (daylight 280-310 nm). Provitamins are precursors to vitamins. They are present in food and are also supplied by the liver (where they are synthesized from cholesterol). Just like plant-based and animal-based foods, breastmilk also contains several provitamins, but only small amounts of vitamin D. Since the only food with a high natural

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content of vitamin D is fish liver oil, consumption of cod-liver oil used to be recommended in order to prevent rickets.

In order to make enough vitamin D, children need to be exposed to bright daylight without being covered up. This means that they need to spend at least 2 hours in the open air in the middle of the day; they do not need to be exposed to direct sunlight (Illing 1998).

Vitamin D deficiency, which can lead to rickets, often occurs in winter and spring due to a lack of light.

Rickets is defined as the defective mineralization of growing bones. It peaks in infants between the ages of 3 and 8 months. Typical symptoms are: weakening of the cranial bones (compressible points, flattening at the back of the head), large fontanelles with soft edges, distension of the ends of the bones and later on a permanent distortion of the bones (funnel chest, knock-knees or bandy legs). These are accompanied by general symptoms such as rapid fatigue, anxiety, perspiration on the head, muscular flaccidity and ligament flaccidity, susceptibility to infection and delayed emergence of the teeth.

Rickets is **treated** with high-dose administration of vitamin D (Vigantol®), e.g. a daily oral dose of 3000-5000 international units (I.U.) over the course of 4-6 weeks. In addition, children are also given oral doses of calcium and phosphate (Niessen 1996). In the event of higher doses, particularly in the case of parenteral high-dose therapy of acute rickets, the risk of vitamin D hypervitaminosis must be taken into account. Symptoms of hypervitaminosis often only occur after several weeks: increased phosphorus and calcium in the serum, calcium deposits in the blood vessels and kidneys, irritability, loss of appetite, constipation, vomiting, muscle hypotonia and impairment of intellectual abilities (Niessen 1996, Goebel 1987).

An infant's **minimum daily requirement** of vitamin D is 400 I.U., corresponding to 10 µg or 0.01 mg of crystalline vitamin D (one I.U. of vitamin D corresponds to 0.025 µg of pure crystalline vitamin D₃).

Premature babies have a higher requirement.

Four options for the prophylaxis of rickets:

Option 1:

Year-round substitution with a daily vitamin D tablet containing 500 I.U. (1000 I.U. for premature babies) is the most reliable method of preventing rickets. The vitamin D is given over the course of a year. Should the child's first birthday fall in the winter, then treatment should be continued until the spring. Babies will be given one Vigantolekten® 500 tablet every day from the start of the second week following their birth, preferably before a breastfeed or bottle feed (combination preparations such as D-Fluoretten®, Fluor-Vigantolekten® or Zymafluor DR®, see p. 260). The tablets disperse quickly in a spoonful of

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water and can be drunk easily from the spoon. Since vitamin D deficiency scarcely features in the first few weeks of life, some pediatricians recommend only starting treatment in the 4th week of life in order to allow the baby's digestive system to develop.

Option 2:

Children are given a daily dose of 500 I.U. of vitamin D in the winter only (October-March). Where babies spend two hours a day in natural daylight in the summer period, either no vitamin D is given or a reduced dose, for example half a tablet (250 I.U.) each day or a whole tablet every other day.

Option 3

In the case of children who are susceptible to allergies, or where increased bloating is experienced after taking the tablets, **Vigantol® oil** (1 drop contains 500 I.U.) can also be recommended instead of tablets in both of the options outlined above. The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil). The customary Vigantolekten® contain eleven excipients, namely silicon dioxide, cornstarch, sodium carboxy methyl starch, talc, glycerol tristearate, cellulose, D-mannitol, gelatin, sucrose, partially-hydrated soybean oil and α -tocopherol. Unfortunately, there are no recommended tablets containing fewer excipients. Virgosan® 500 contains lactose (milk sugar), Vitamin D₃-Hevert® is only available in a strength of 1000 I.U. per tablet ('Rote Liste' drug compendium 2001). I consider the long list of additives in the tablets to be worrying for familial allergies and would recommend vitamin D oil instead.

Vigantol® oil is a prescription-only medicine, as there is a risk of an overdose if it is not used properly. Before asking their pediatrician for a prescription, parents must be given full details of the benefits and drawbacks of the oil, and also of its use; if this is not done, their pediatrician will refuse to prescribe the oil for fear of incorrect dosage.

Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be put directly in the baby's mouth! Should 2 drops fall onto the spoon, the spoon should be washed and the process started again. In my experience, skeptical parents are more likely to be accepting of administering drops on a daily basis than a daily dose of tablets. I have also now been able to convince some pediatricians of the advantages of the oil.

Option 4:

In anthroposophic medicine, prophylactic administration of synthetically produced vitamin D is regarded as problematic, owing, inter alia, to the potential impact on the child's mental development "in the sense of early intellectualization and failing to develop thoughts independently" (Goebel 1987). For this reason, **endogenous synthesis of vitamin D** should be primarily promoted; a general, artificial substitute is opposed. With the appropriate lifestyle (the child needs to sit by an open window, on the balcony or outside with his/her

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head uncovered for 2 hours each day), there is no need to administer vitamin D, provided that the child is checked every four weeks for symptoms of rickets. Where daylight is in short supply, daily sunlamp treatment can be used to increase the child's vitamin D synthesis. The naked child is held in its mother's arm or on her lap and is exposed to UV light for 30 seconds on his/her abdomen and back, slowly increasing to a maximum of 2 minutes on each side. Caution: babies and mothers must always wear eye protection! In the event of erythema, reduce the time! (Goebel 1987).

Maternal vitamin D intake: Many mothers ask whether they can take vitamin D themselves and pass it onto their babies via breastmilk. Although where mothers take Vigantol® vitamin D and its by-products pass into breastmilk ("Rote Liste" 2001), unfortunately no recommendation exists in this respect, because research has not been carried out into the exact quantity.

Industrially produced infant nutrition almost always contains a vitamin D supplement, meaning that the minimum daily requirement of 400 I.U. (10 µg of crystalline vitamin D₃) is met in part by supplementing infant food. Although some authors (Gahr 1994, Illing 1998) consider double administration to be harmless, when parents ask me about this I recommend calculating the daily vitamin D amount in infant food based on the package label and amount of daily drink and reducing the prophylaxis accordingly, so that their child receives a maximum dose of 500 I.U. of vitamin D each day, because "more doesn't always mean better", and it is better to avoid an overdose.

? Do newborn babies need to take daily fluoride tablets?

No, since from a dental perspective no fluoridization measures to prevent tooth decay are required before the age of six months.

Tooth decay is not caused by a fluoride deficiency, and so taking fluoride tablets before the first milk teeth have erupted is not effective (German Society for Dental and Oral Medicine, DGZMK March 2000).

The combination preparations containing vitamin D and fluoride (D-Fluoretten®, Fluor-Vigantolekten® or Zymafluor DR®) for the prophylaxis of rickets and tooth decay which have been recommended by dentists and pediatricians for years now can no longer be recommended on the basis of current scientific knowledge.

Several studies have shown that fluoride primarily works to inhibit tooth decay through direct contact with the surface of the tooth. For this reason, when using fluorides, local application (toothpaste) takes precedence over the systemic route (tablets). In recent years, in the Scandinavian countries and in the USA and Canada, for example, fluoride tablets have only

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been recommended for children who are at risk of tooth decay (children with severe dental caries) and in most cases only starting from the age of three.

The cornerstone of effective prophylaxis of tooth decay:

- A balanced diet (preferably no sugar or white flour products, or only small quantities thereof)
- Daily brushing of teeth (twice a day from the age of three)
- Use of fluorides (primarily through increasing the fluoride concentration in the region of the surface of the teeth).

It is only once the milk teeth have erupted (at 6-7 months) that the hardness of the tooth enamel can be improved by a local increase in fluoride ion concentration on the enamel. Dentists therefore recommend brushing children's teeth daily using a small, soft-bristled toothbrush and no bigger than a pea-sized amount of fluoride-containing children's toothpaste. In order to discourage children from swallowing any toothpaste, children's toothpastes should not be fruit or candy flavored.

Different recommendations: Unfortunately, many pediatricians do not agree with the DGZMK's dental recommendation, continuing to prescribe a daily dose of 0.25 mg of fluoride combined with 500 I.U. of vitamin D to infants from the age of ten days. Although they acknowledge that the proven lack of benefit of the administration of fluoride in the first year of life is scientifically correct, they continue to adhere to the old recommendation. According to the German Society for Pediatrics, the use of vitamin D preparations is an unnecessary complication for prophylactic prescriptions. This behavior is difficult to explain, as the tablets for the prophylaxis of rickets and tooth decay are prescribed by pediatricians, and vitamin D can be prescribed without fluoride substitution without any problems (see above).

It is absurd to prescribe unnecessary fluoride to infants for six months! The halogen fluoride is a highly effective cytotoxin, which is lethal in amounts of 5-15 g (Daudeker 1995, Lewin 1992). A **fluoride overdose** can lead to dental fluorosis, which manifests itself as whitish or brown marks on the enamel of the permanent teeth. Some of the regularly ingested fluoride is stored in the bones. As it suppresses calcium phosphate, particularly in the growth core, daily fluoride intake can be the cause of a constricted jaw and premature aging of the bones in the second half of life. Other side effects can be: poor concentration, forgetfulness, parathyroid hypofunction, porosity of the bones resulting in extreme bone damage (Daudeker 1995, Barmer Lexikon Gesundheit und Medizin).

When providing advice to parents, midwives and pediatricians are caught in the middle of the different recommendations. In light of the evidence-based guidelines of the DGZMK, I am no longer able to recommend fluoride tablets to prevent tooth decay. When it comes to

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post-partum care, I will inform parents of the current scientific knowledge and the disagreement among dental and pediatric associations; it will then be up to parents to make the decision.

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Abb. 15.11 Blutentnahme für das Neugeborenen-Screening. Hannah liegt aufrecht auf dem Arm der Mutter, so kann das Blut besser fließen.

Hautkontakt zwischen Mutter und Baby kann den Schmerz für das Neugeborene verringern. In einer Studie (Wyatt/Blass 2000) zeigten die Kinder der Gruppe mit Hautkontakt beim Fersenstich 82 % weniger Weinen und 65 % weniger Grimassieren, als Kinder der Kontrollgruppe; der Hautkontakt bewirkte auch eine geringere Beschleunigung der Herzfrequenz. Am günstigsten finde ich es, wenn das Kind bei der Blutentnahme von Mutter oder Vater aufrecht auf dem Arm getragen wird (Abb. 15.11), so fließt das Blut leichter als im Liegen mit hochgerecktem Bein. Soll die Blutentnahme auf dem Wickeltisch erfolgen, bitte ich die Mutter, eine Hand an den Kopf des Kindes zu legen und mit der anderen das freie Beinchen zu halten und zu streicheln.

Die markierten Kreise auf der Filzkarte müssen zügig nacheinander betropft werden, so dass das Blut auch auf der Rückseite sichtbar wird, dabei die Kreise möglichst großflächig durchtränken. Bleibt ein Eckchen ohne Blut, sollte der angetrocknete Kreis nicht mehr nachbetropft werden, da sonst eine zu dicke Blutschicht entsteht. Das Labor stanzt je nach Anzahl der Untersuchungen viele kleine Areale aus den gleichmäßig betropften Stellen der Filzpappe, die Kreise werden nicht komplett ausgestanzt.

Die Karte muss bei Zimmertemperatur 3 Stunden getrocknet werden (nicht auf der Heizung oder in der Sonne), bevor sie in einem Briefumschlag mit Begleitzettel zum Labor gesandt wird.

15.9 Blutungs-, Rachitis- und Kariesprophylaxe

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|--|--------|
| ❓ Warum bekommt das Kind Vitamin-K-Tropfen? | S. 256 |
| ❓ Sind Vitamin-D-Tabletten für jedes Kind notwendig? | S. 257 |
| ❓ Braucht das Neugeborene täglich Fluor-Tabletten? | S. 260 |

❓ Warum bekommt das Kind Vitamin-K-Tropfen?

Vitamin K wird zur Blutgerinnung benötigt. Fast jedes Neugeborene verfügt bei seiner Geburt über ein ausreichendes körpereigenes Vitamin-K-Depot, um in den nächsten Lebenswochen die Blutgerinnung zu garantieren (Muttermilch enthält kaum Vitamin K, und die kindlichen Darmbakterien sind erst nach eini-

gen Wochen in der Lage, es selbstständig zu bilden).

Ein Vitamin-K-Mangel kann beim Kind zwischen der 1.–12. Lebenswoche zu einer erhöhten Blutungsneigung führen.

Diese zeigt sich z.B. am Weiterbluten der Punktionsstelle nach Blutentnahmen, als Schleimhautblutung bei Intubation oder Magensondenlegung, als blutiger Stuhl, als Nabelschnurblutung oder Hirnblutung.

Spuckt ein Neugeborenes in den ersten Lebenstagen Blut, sollte zunächst die häufigste Ursache dieses Phänomens durch Nachfragen abgeklärt werden: Meistens hat das Kind mütterliches Blut verschluckt, entweder bei der Geburt (z.B. blutiges Fruchtwasser, große Episiotomie, Sectio) oder durch Saugen an einer blutigen Brustwarze.

Der Zusammenhang zwischen einem Vitamin-K-Mangel und Blutungen bei Säuglingen ist seit 60 Jahren bekannt und kann bei ca. 1 % der Kinder vorkommen (Tönz 1990). Da niemand genau weiß, ob das Neugeborene genug Vitamin K in der Leber gespeichert hat, wurde ab den 60er Jahren die prophylaktische Aufstockung des Vitamin-K-Depots für Risikokinder empfohlen (z.B. nach operativer Entbindung, nach Frühgeburt oder kindlicher Blutung).

Dosierung:

Seit 1986 rät die Ernährungskommission der Deutschen Gesellschaft für Kinderheilkunde bei allen Neugeborenen nach der Geburt das Vitamin-K-Depot prophylaktisch zu ergänzen. Zunächst wurde als Prophylaxe die einmalige intramuskuläre oder subkutane Injektion von 1 mg Vitamin K nach der Geburt empfohlen. Nachdem in einer britischen Studie (Golding et al. 1992) ein Zusammenhang zwischen intramuskulären Gaben von Vitamin K und vermehrt auftretenden Krebserkrankungen im Kindesalter aufgezeigt wurde, änderte die Kommission 1992 ihre Empfehlung zu einer dreimaligen oralen Gabe von je 1 mg Vitamin K um. 1994 verdoppelte die Ernährungskommission die orale Dosis, da wieder mehr Fälle von Vitamin-K-Mangelblutungen beobachtet wurden.

Heute erhalten fast alle Neugeborenen dreimal eine orale Gabe von **2 mg Vitamin K**.

Die Eltern müssen vorher aufgeklärt werden und der Prophylaxe zustimmen. Das Kind bekommt entweder 2 Tropfen **Kanavit®** Tropfen oder eine 0,2 ml Ampulle **Konaktion®** 2 mg direkt in den Mund. Die erste Gabe erfolgt durch die Hebamme nach der Geburt (U1), zwei weitere Gaben durch den Kinderarzt bei den Vorsorgeuntersuchungen U2 und U3. Jede Vitamin-K-Gabe muss im gelben Kinderuntersuchungsheft dokumentiert werden.

Die erste Vitamin-K-Gabe sollte das Baby übrigens erst bekommen, nachdem es ausgiebig an der Brust gesaugt hat. Zum einen wird das fettlösliche Vitamin K zusammen mit Kolostrum besser aufgenommen, zum anderen kann so das Neugeborene zuerst den Geschmack von Muttermilch kennen lernen, bevor es mit dem Fremdgeschmack der Tropfen konfrontiert wird (Konaktion® schmeckt wie die Gummierung einer Briefmarke).

Für die orale Vitamin-K-Prophylaxe sind keine Nebenwirkungen beschrieben, es kann aber nicht ausgeschlossen werden, dass durch den frühen Kontakt mit den Inhaltsstoffen der Lösung die Allergiebereitschaft eines Kindes heraufgesetzt wird (Konaktion® 2 mg enthält: Lecithin u. Glycocholsäure aus Sojabohnen, Natriumhydroxyd, Salzsäure, Wasser, Vitamin K1. Kanavit® Tropfen enthalten: Polysorbat, Sorbinsäure, Wasser, Vitamin K1). Lehnen Eltern aus diesem oder einem anderen Grund die Prophylaxe ab, ist das von allen Betreuern zu akzeptieren, denn in Deutschland besteht keine Pflicht, sich an Prophylaxen zu beteiligen.

? Sind Vitamin-D-Tabletten für jedes Kind notwendig?

Die Vorstellung, einem gesunden Säugling jeden Tag eine Tablette zu geben, erzeugt bei vielen Eltern ein gewisses Unbehagen. Das ist verständlich, denn in der Regel werden ja Tabletten zur Behandlung von Krankheiten verordnet. Die tägliche Vitamin-D-Tablette hingegen behandelt keine Erkrankung, sondern soll eine

möglicherweise auftretende Rachitis-Erkrankung vorbeugen. Damit sich die Eltern eindeutig für eine Art der **Rachitisprophylaxe** (s.u.) entscheiden können, brauchen Sie von Kinderarzt, Hebamme und Kinderkrankenschwester genaue Informationen zu Vitamin D und Rachitis.

Vitamin D wird vom Kind zur Kalziumeinlagerung und damit zur Verfestigung der Knochen benötigt, es fördert auch die Kalzium- und Phosphatresorption aus dem Darm. Ein Säugling stellt sein Vitamin D selbst her, indem er unter Einwirkung von ultraviolettem Licht (Tageslicht 280–310 nm) Provitamine in der Haut zu Vitamin D umwandelt. Provitamine sind Vorstufen des Vitamins, sie kommen in der Nahrung vor und werden zusätzlich von der Leber (aus Cholesterin synthetisiert) bereitgestellt. Muttermilch enthält ebenso wie pflanzliche und tierische Nahrungsmittel etliche Provitamine, aber nur wenig Vitamin D. Das einzige Lebensmittel mit hohem natürlichen Vitamin-D-Gehalt ist Fischleberöl, daher wurde früher die Einnahme von Lebertran zur Rachitisprophylaxe empfohlen.

Um ausreichend Vitamin D zu bilden, muss das Kind täglich unverdecktem, hellen Tageslicht ausgesetzt sein, das heißt es muss sich mindestens 2 Stunden um die Tagesmitte im Freien aufhalten, direkte Sonneneinstrahlung ist nicht nötig (Illing 1998).

Wegen Lichtmangel tritt im Winter und Frühling oft ein Vitamin-D-Mangel auf, der zur Rachitis führen kann.

Als **Rachitis** wird eine mangelnde Mineralisation der wachsenden Knochen bezeichnet. Der Erkrankungsgipfel liegt im 3.–8. Lebensmonat. Typische Symptome sind: Erweichung der Schädelknochen (eindrückbare Stellen, Abflachung des Hinterkopfes), weite Fontanellen mit weichen Rändern, Auftreibung von Knochenenden und später eine bleibende Knochenverkrümmung (Trichterbrust, X- oder O-Beine). Dazu kommen Allgemeinsymptome wie rasche Ermüdbarkeit, Unruhe, Kopfschweiß, Muskel- und Bänderschläffheit, Infektanfälligkeit sowie ein später Zahndurchbruch.

Behandelt wird die Rachitis mit hochdosierten Vitamin-D-Gaben (Vigantol®), z.B. täglich oral 3000–5000 Internationale Einheiten (I.E.) über 4–6 Wochen, zusätzlich erhält das Kind oral Kalzium und Phosphat (Niessen 1996). Bei einer Höherdosierung, besonders bei der parenteralen Stoßtherapie der akuten Rachitis, muss auf die Gefahr einer Vitamin-D-Hypervitaminose geachtet werden. Deren Symptome treten oft erst nach mehreren Wochen auf: Erhöhung von Phosphor und Kalzium im Serum, Kalziumablagerungen in Blutgefäßen und Niere, Reizbarkeit, Appetitmangel, Obstipation, Erbrechen, Muskelhypotonie und Beeinträchtigung der geistigen Fähigkeiten (Niessen 1996, Goebel 1987).

Der **tägliche Mindestbedarf** eines Säuglings an Vitamin D liegt bei 400 I.E., das entspricht 10 µg bzw. 0,01 mg kristalinem Vitamin D (eine I.E. Vitamin D entspricht 0,025 µg reinem kristalinem Vitamin D₃).

Frühgeborene haben einen höheren Bedarf.

Vier Wege der Rachitisprophylaxe:

1. Weg:

Ganzjährige Substitution mit täglich einer Vitamin-D-Tablette zu 500 I.E. (Frühgeborene 1000 I.E.) gilt als sicherste Rachitis-Prophylaxe. Das Vitamin D wird ein Jahr lang gegeben. Liegt der 1. Geburtstag im Winter, sollte die Prophylaxe sicherheitshalber bis zum Frühjahr des nächsten Jahres fortgeführt werden. Das Baby erhält ab der 2. Lebenswoche täglich 1 Tablette Vigantoletten® 500, am besten vor einer Still- oder Flaschenmahlzeit (Kombinationspräparate wie D-Fluoretten®, Fluor-Vigantoletten® oder Zymafluor DR® s.S. 260). Auf einem Löffel Wasser zerfallen die Tabletten rasch, und können leicht vom Löffel getrunken werden. Da der Vitamin-D-Mangel in den ersten Lebenswochen kaum eine Rolle spielt, empfehlen einige Pädiater mit der Prophylaxe erst in der 4. Lebenswoche zu beginnen, damit sich vorher die Verdauung des Babys einspielen kann.

2. Weg:

Nur im Winterhalbjahr (Oktober–März) erhält das Kind täglich 500 I.E. Vitamin D. Kommt das Baby im Sommerhalbjahr täglich 2 Stunden ins freie Tageslicht, wird auf die Vitamin-D-Gabe verzichtet oder eine reduzierte

Dosis gegeben, das Kind bekommt z.B. täglich eine halbe (250 I.E.) Tablette oder alle 2 Tage eine ganze.

3. Weg:

Bei **allergischer Disposition** oder wenn sich durch die Tabletten-Einnahme Blähungen verstärken, kann für beide oben beschriebenen Wege statt Tabletten auch **Vigantol® Öl** (1 Tropfen enthält 500 I.E.) empfohlen werden. Das Öl hat sich über viele Jahre bewährt und enthält nur einen Hilfsstoff als Trägersubstanz für das fettlösliche Vitamin D, nämlich mittelkettige Triglyceride (Pflanzenöl). Die üblichen Vigantolelletten® enthalten elf Hilfsstoffe, nämlich Siliciumdioxid, Maisstärke, Carboxymethylstärke-Natrium, Talkum, Glyceroltristearat, Cellulose, D-Mannitol, Gelatine, Saccharose, teilhydriertes Sojaöl und α -Tocopherol. Leider gibt es keine empfehlenswerte Tablette mit weniger Hilfsstoffen. Virgosan® 500 enthält Lactose (Milchzucker), Vitamin D₃-Hevert® gibt es nur mit 1000 I.E. pro Tablette (Rote Liste 2001). Bei familiärer Allergiebelastung halte ich die lange Zutatenliste der Tabletten für bedenklich und empfehle lieber Vitamin-D-Öl.

Vigantol® Öl ist verschreibungspflichtig, da bei unsachgemäßer Handhabung die Gefahr einer Überdosierung besteht. Bevor die Eltern ihren Kinderarzt um ein Rezept bitten, müssen sie über die Vor- und Nachteile des Öls genau aufgeklärt werden, ebenso über seine Anwendung, denn sonst lehnt ihr Kinderarzt die Verschreibung aus Angst vor falscher Dosierung ab.

Die **Anwendung** ist einfach: Einmal täglich vor dem Stillen bzw. der Mahlzeit wird 1 Tropfen Vigantol® Öl vorne auf einem Löffel dem Baby zum Ablecken gegeben. Es darf nie direkt in den Mund getropft werden! Fallen 2 Tropfen auf den Löffel, kann er abgewischt und neu betropft werden. Nach meiner Beobachtung wird die Tropfen-Einnahme von kritischen Eltern eher akzeptiert und täglich ausgeführt, als eine tägliche Tabletten-Einnahme. Mittlerweile konnte ich auch einige Kinderärzte von den Vorzügen des Öls überzeugen.

4. Weg:

In der **anthroposophischen Medizin** wird die prophylaktische Gabe von synthetisch hergestelltem Vitamin D als problematisch ange-

sehen, unter anderem wegen einer möglichen Auswirkung auf die seelische Entwicklung des Kindes „im Sinne einer Disposition zur Früh-intellektualisierung und Verunselbstständigung im Denken“ (Goebel 1987). Darum soll vorrangig die **Eigenbildung von Vitamin D gefördert** werden, eine generelle, künstliche Substitution wird abgelehnt. Bei entsprechender Lebensführung (das Kind muss täglich 2 Stunden am offenen Fenster, auf dem Balkon oder draußen mit unbedecktem Kopf direkt unter hellem Himmel sein) kann auf Vitamin-D-Gaben verzichtet werden, wenn eine vierwöchige Kontrolle des Kindes auf Rachitis-Symptome gewährleistet ist. Bei mangelndem Tageslicht besteht die Möglichkeit, durch tägliche Höhensonnen-Behandlung die Vitamin-D-Bildung des Kindes zu steigern. Das Kind wird dazu täglich nackt auf dem Arm/Schoß der Mutter mit UV-Licht bestrahlt, anfangs auf Bauch- und Rückenseite je eine halbe Minute, dann langsam steigern auf maximal 2 Minuten je Seite. Achtung: Immer Augenschutz für Kind und Mutter! Bei Hautrötung die Zeit reduzieren! (Goebel 1987).

Mütterliche Vitamin-D-Einnahme: Manche Mütter fragen, ob sie selbst Vitamin D einnehmen und über die Muttermilch an ihr Baby weitergeben können. Obwohl bei einer mütterlichen Vigantol®-Einnahme Vitamin D und seine Abbauprodukte in die Muttermilch übergehen (Rote Liste 2001), gibt es dazu leider keine Empfehlung, denn die genaue Menge ist nicht erforscht.

Industriell hergestellte Säuglingsnahrung enthält fast immer einen Vitamin-D-Zusatz, so dass der tägliche Mindestbedarf von 400 I.E. (10 µg kristallines Vitamin D₃) durch Zufüttern von Säuglingsnahrung teilweise abgedeckt wird. Auch wenn einige Autoren (Gahr 1994, Illing 1998) die Doppelgabe für unbedenklich halten, empfehle ich diesbezüglich nachfragenden Eltern, die tägliche Vitamin-D-Menge in der Säuglingsnahrung anhand von Packungsbeschriftung und Tagestrinkmenge auszurechnen und die Prophylaxe entsprechend zu reduzieren, so dass ihr Kind täglich maximal 500 I.E. Vitamin D erhält, denn „viel hilft ja nicht immer viel“, und eine Überdosierung sollte besser vermieden werden.

? Braucht das Neugeborene täglich Fluor-Tabletten?

Nein, denn vor dem 6. Lebensmonat sind aus zahnärztlicher Sicht keine Fluorisierungsmaßnahmen zur Karies-Prophylaxe erforderlich.

Karies ist keine Fluoridmangelerkrankung, daher ist die Einnahme von Fluor-Tabletten vor dem Durchbruch der ersten Milchzähne nicht wirksam (Deutsche Gesellschaft für Zahn-, Mund- und Kieferheilkunde, DGZMK März 2000).

Die jahrelang von Zahn- und Kinderärzten angeratenen Kombinationspräparate zur Rachitis-Karies-Prophylaxe mit Vitamin D und Fluor (D-Fluoretten®, Fluor-Vigantolekten® oder Zymafluor DR®) können aufgrund aktueller wissenschaftlicher Erkenntnisse nicht mehr empfohlen werden.

Mehrere Untersuchungen haben gezeigt, dass Fluorid in erster Linie durch den direkten äußerlichen Kontakt am Zahn karieshemmend wirkt. Darum ist beim Einsatz von Fluoriden der lokalen Applikation (Zahnpasta) gegenüber der systemischen Zufuhr (Tabletten) der Vorrang einzuräumen. In den letzten Jahren wurde die Einnahme von Fluor-Tabletten z.B. in Skandinavien, USA und Kanada nur noch für Kariesrisikokinder (Kinder mit erheblichem Kariesbefall) und meistens auch erst ab dem 3. Lebensjahr empfohlen.

Eckpfeiler einer guten Kariesprophylaxe:

- Ausgewogene Ernährung (möglichst keine oder nur wenig Zucker- und Weißmehlprodukte)
- Tägliche Zahnreinigung (ab dem 3. Lebensjahr 2-mal täglich)
- Anwendung von Fluoriden (primär durch Erhöhung der Fluoridkonzentration im Bereich der Zahnoberfläche).

Erst nach dem Durchbruch der Milchzähne

(6.-7. Lebensmonat) lässt sich die Härte des Zahnschmelzes durch eine lokale Erhöhung der Fluoridionenkonzentration am Zahnschmelz verbessern. Zahnärzte, empfehlen darum, die Zähne täglich mit einer kleinen,

weichen Zahnbürste und einer maximal erbsengroßen Menge fluoridhaltiger Kinderzahn-paste zu reinigen. Um keinen Anreiz zum Herunterschlucken zu geben, sollte die Kinderzahn-paste keinen Frucht- oder Bonbon-geschmack haben.

Unterschiedliche Empfehlungen: Leider stimmen viele Kinderärzte der zahnärztlichen Empfehlung der DGZMK nicht zu und verschreiben Säuglingen ab dem 10. Lebenstag weiterhin täglich 0,25 mg Fluorid in Kombination mit 500 I.E. Vitamin D. Obwohl sie den nachweislich fehlenden Nutzen der Fluorgaben im ersten Lebensjahr als wissenschaftlich korrekt anerkennen, halten sie weiter an der alten Empfehlung fest. Nach Ansicht der Deutschen Gesellschaft für Kinderheilkunde würde die Verwendung von Vitamin-D-Präparaten die Prophylaxen-Verschreibung unnötig verkomplizieren. Diese Haltung ist schwer nachvollziehbar, denn die Tabletten zur Rachitis- und Kariesprophylaxe werden von Kinderärzten verschrieben, und Vitamin D kann problemlos ohne Fluoridsubstitution verordnet werden (s.o.).

Es ist absurd, Säuglingen ein halbes Jahr unnötigerweise Fluor zu verabreichen! Das Halogen Fluor ist ein hochwirksames Zellgift, das bei Einnahme von 5–15 g tödlich wirkt (Daunerer 1995, Lewin 1992). Eine **Fluorüberdosierung** kann zur Dentalfluorose führen, welche sich als weißliche oder bräunliche Flecken auf dem Zahnschmelz der bleibenden Zähne zeigt. Das regelmäßig eingenommene Fluorid wird zum Teil im Knochen eingelagert. Da es besonders in den Wachstums-kernen das Kalziumphosphat verdrängt, kann die tägliche Fluor-Einnahme die Ursache für einen zu engen Kiefer sowie für eine vorzeitige Knochenalterung in der zweiten Lebenshälfte sein. Weitere Nebenwirkungen können sein: Konzentrations-schwäche, Vergesslichkeit, Nebenschilddrüsen-Unterfunktion, Porosität der Knochen bis zur Knochenzerstörung (Daunerer 1995, Barmer Lexikon Gesundheit und Medizin).

Bei der Beratung der Eltern stehen Hebamme und Kinderkrankenschwester im Spannungsfeld der unterschiedlichen Empfehlungen. Angesichts der evidenzbasierten Leitlinien der DGZMK kann ich heute keine Kariesprophylaxe

mit Fluor-Tabletten mehr empfehlen. Im Rahmen der Wochenbettbetreuung werden die Eltern von mir über den momentanen Stand der Wissenschaft und über die Uneinigkeit der

zahnärztlichen und kinderärztlichen Vereinigungen informiert, entscheiden müssen sie dann selbst.

15.10 Schadstoffe und Umweltgifte

- | | |
|---|---|
| <p>? Können Rückstände in meiner Muttermilch das Kind beeinträchtigen?</p> <p>? Warum muss neue Babykleidung immer 1–2mal gewaschen werden?</p> <p>? Unsere Kinderzimmermöbel riechen noch sehr neu, ist das ungesund fürs Baby?</p> <p>? Welcher Fußboden im Kinderzimmer ist besser, Laminat oder Teppichboden?</p> | <p>S. 261</p> <p>S. 262</p> <p>S. 262</p> <p>S. 262</p> |
|---|---|

? Können Rückstände in meiner Muttermilch das Kind beeinträchtigen?

Leider ist heute die Muttermilch vieler Frauen so stark mit **Schadstoffen belastet**, dass sie nach geltendem Lebensmittelrecht nicht zum Verzehr zugelassen würde (Neuburger 1996). Dabei handelt es sich um **Speichergifte**, die mit Nahrung, Trinkwasser, Atemluft und über die Haut in den Organismus aufgenommen werden und nur zu einem kleinen Teil wieder ausgeschieden werden können.

Besonders fettlösliche Substanzen wie Insektizide (z.B. DDT, DDE, Lindan, PCP), Fungizide (HCB), Furane und Dioxine sowie die Industriechemikalie PCB lagern sich im Fettgewebe ein, von wo aus sie in die Muttermilch gelangen. In der Muttermilch befinden sich auch oft erhöhte Konzentrationen von Schwermetallen wie Quecksilber (Amalgamfüllungen, Meeresfrüchte), Blei (Straßenstaub, Müllverbrennung), Platin und Palladium (Autoabgase, Straßenstaub, Dentallegierungen), Cadmium (Kunststoffe, Farben), Arsen (Seefische, Algen, Müllverbrennung) etc. Viele dieser Stoffe sind Nerven-, Hirn und Lebergifte, andere sind allergen, nierenschädigend, krebserregend, fruchtschädigend, usw.

Dennoch wird Muttermilch dank ihrer besonderen Zusammensetzung von der nationalen Stillkommission noch immer als das vorteilhafteste Nahrungsmittel für Säuglinge angesehen (s. S. 88), wobei die Nachteile durch die Schadstoffbelastung in Kauf genommen werden können/müssen.

Es ist deprimierend, dass wir Menschen unser ureigenstes Nahrungsmittel Muttermilch durch Konsumverhalten, Fortschrittsglauben und wirtschaftliche Interessen (Chemische Industrie etc.) derart beeinträchtigt haben. Im Interesse unserer Kinder sind Umdenken und Verhaltensänderungen bei jedem Einzelnen und der Politik zu fordern.

- **Um die Belastung des Säuglings durch Schadstoffe aus der Muttermilch möglichst gering zu halten**, sollte die Mutter während der Stillzeit den Verzehr höher belasteter Nahrungsmittel wie Innereien, tierische Fette, Fisch (Empfehlung des Bundesinstituts für gesundheitlichen Verbraucherschutz 1999), Meeresfrüchte, Algen und Wildpilze einschränken oder, wenn möglich, ganz darauf verzichten.
- Da eine starke Gewichtsreduktion eingelagerte Schadstoffe aus dem Fettgewebe mobilisiert, raten wir in der Stillzeit nicht zu viel abzunehmen und auf keinen Fall mit dem Gewicht unter das Ausgangsgewicht von vor der Schwangerschaft zu sinken.
- Amalgamfüllungen sollten während der Schwangerschaft und Stillzeit weder entfernt, noch neu gelegt werden (Bundesinstitut für Arzneimittel und Medizinprodukte 1995).
- Besteht Verdacht auf eine starke Schwermetall- oder Insektizidbelastung der Muttermilch (z.B. bei starken Blähungen s.S.246, mangelnder Gewichtszunahme, Gedeih- und

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Reinhold W. Vieth et al.
U.S. Patent No.: 9,066,958 Attorney Docket No. 53953-0001IP1
Issue Date: June 30, 2015
Appl. Serial No.: 11/674,234
Filing Date: February 13, 2007
Title: VITAMIN D COMPOSITIONS AND METHOD OF
ADMINISTRATION TO A HUMAN BEING

DECLARATION OF ACCURACY OF TRANSLATION

I, David Joshua SHERMAN, hereby declare as follows:

1. Rebecca Amy TINWORTH performed the attached translation from German into English of Chapter 15.9 of "Wochenbettbetreuung in der Klinik und zu Hause" [Childbed care in clinics and at home] (also attached).
2. Rebecca Amy TINWORTH is competent to perform this translation, because she has a Bachelor of Arts (Honors) degree in German studies.
3. I have reviewed the translation and confirm that the addition of "to be licked off" (for the German "zum Ablecken") on page 4 of the translation in the fifth line of the second paragraph under Option 3 makes the translation a more accurate reflection of the German text.
4. I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct; and further declare that I am aware that willful false statements and the like so made are punishable by fine or imprisonment, or both.

Dated: February 28, 2023



David Sherman
UK Head of Translation Operations –
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15.9 Prophylaxis of bleeding, rickets and tooth decay

?	Why are babies given vitamin K drops?	p. 256
?	Do all babies need vitamin D tablets?	p. 257
?	Do newborn babies need to take daily fluoride tablets?	p. 260

? Why are babies given vitamin K drops?

Vitamin K is needed to help the blood to clot. Almost all newborn babies have sufficient stores of vitamin K in their bodies at birth to ensure that the blood will clot in the next few weeks of their life (breastmilk contains hardly any vitamin K, and intestinal bacteria in babies are not capable of synthesizing it themselves for the first few weeks after birth).

Vitamin K deficiency in babies aged between 1 and 12 weeks can lead to increased tendency to bleed.

This manifests itself in continued bleeding at the site of injection following the taking of a blood sample, in bleeding of the mucous membranes in the event of intubation or the insertion of a feeding tube, as well as in blood in the stools, bleeding of the umbilical cord or cerebral bleeding.

If a newborn baby is spitting-up blood in the first few days after birth, questions should be asked to clarify the most common causes of this phenomenon: in most cases, the baby will have swallowed blood from its mother, either during the birth (e.g. amniotic fluid containing blood, large episiotomy, Caesarean section) or through feeding from a bleeding nipple.

The connection between vitamin K deficiency and bleeding in infants was established 60 years ago and can occur in around 1% of children (Tönz 1990). As there is no way of knowing whether newborn babies have sufficient stores of vitamin K in their liver, prophylactic increase of vitamin K stores for at-risk children (e.g. following surgical delivery, premature birth or bleeding in children) has been recommended since the 1960s.

Dosage:

Since 1986, the German Association for Pediatrics' Committee on Nutrition advised that all neonates should be given a prophylactic dose of vitamin K following birth. Initially, a single intramuscular or subcutaneous injection of 1 mg of vitamin K was recommended prophylactically after birth. Following the establishment by a British study (Golding et al. 1992) of a connection between the intramuscular administration of vitamin K and an increase in the number of cases of childhood cancers, in 1992 the Committee amended its recommendation to three oral administrations, each containing a 1 mg dose of vitamin K. In

1994, the Committee on Nutrition doubled the oral dose, due to more cases of bleeding as a result of vitamin K deficiency being observed once again.

Nowadays, nearly all neonates receive three doses of 2 mg of vitamin K orally.

Parents must be consulted beforehand and must agree to the prophylaxis. Babies will receive either 2 drops of **Kanavit®** drops or a 0.2 ml ampoule of **Konakion®** 2 mg directly into their mouths. The first dose is given by the midwife following birth (check-up 1), followed by two further doses by a pediatrician at medical check-ups 2 and 3. Each administration of vitamin K must be documented in the child's yellow medical check-up booklet.

Babies should not receive **the first dose of vitamin K** until they have had a lengthy feed at the breast. This is because, firstly, vitamin K is liposoluble and is better absorbed with colostrum, and secondly it gives neonates the chance to familiarize themselves with the taste of breastmilk before being confronted with the foreign taste of the drops (Konakion® tastes like the adhesive coating on a postage stamp).

Although no side effects have been described for the oral prophylaxis of vitamin K, the possibility that early contact with the ingredients contained in the solution may increase a child's disposition to allergies cannot be ruled out (Konakion® 2 mg contains: lccithin and glycocholic acid from soya beans, sodium hydroxide, hydrochloric acid, water, vitamin K1. Kanavit® drops contain: polysorbate, sorbic acid, water, vitamin K1). Where parents do not give their consent to the prophylaxis for this reason or for other reasons, all caregivers must accept this; in Germany, there is no obligation to take part in prophylaxes.

? Do all children need vitamin D tablets?

Many parents are uncomfortable with the idea of giving a healthy infant a tablet each day. This is understandable, given that tablets are usually prescribed to treat illnesses. The daily vitamin D tablet, by contrast, does not treat an illness, but is designed to prevent the possible occurrence of rickets. Parents need to be given accurate information on vitamin D and rickets by pediatricians, midwives and pediatric nurses so that they can make an informed decision with regard to a form of **rickets prophylaxis** (see below).

Children need **vitamin D** to store calcium, which in turn is needed to strengthen bones. Vitamin D also promotes the absorption of calcium and phosphate from the intestine. Infants produce their own vitamin D by converting provitamins in the skin to vitamin D under the effect of ultraviolet light (daylight 280-310 nm). Provitamins are precursors to vitamins. They are present in food and are also supplied by the liver (where they are synthesized from cholesterol). Just like plant-based and animal-based foods, breastmilk also contains several provitamins, but only small amounts of vitamin D. Since the only food with a high natural

content of vitamin D is fish liver oil, consumption of cod-liver oil used to be recommended in order to prevent rickets.

In order to make enough vitamin D, children need to be exposed to bright daylight without being covered up. This means that they need to spend at least 2 hours in the open air in the middle of the day; they do not need to be exposed to direct sunlight (Illing 1998).

Vitamin D deficiency, which can lead to rickets, often occurs in winter and spring due to a lack of light.

Rickets is defined as the defective mineralization of growing bones. It peaks in infants between the ages of 3 and 8 months. Typical symptoms are: weakening of the cranial bones (compressible points, flattening at the back of the head), large fontanelles with soft edges, distension of the ends of the bones and later on a permanent distortion of the bones (funnel chest, knock-knees or bandy legs). These are accompanied by general symptoms such as rapid fatigue, anxiety, perspiration on the head, muscular flaccidity and ligament flaccidity, susceptibility to infection and delayed emergence of the teeth.

Rickets is **treated** with high-dose administration of vitamin D (Vigantol®), e.g. a daily oral dose of 3000-5000 international units (I.U.) over the course of 4-6 weeks. In addition, children are also given oral doses of calcium and phosphate (Niessen 1996). In the event of higher doses, particularly in the case of parenteral high-dose therapy of acute rickets, the risk of vitamin D hypervitaminosis must be taken into account. Symptoms of hypervitaminosis often only occur after several weeks: increased phosphorus and calcium in the serum, calcium deposits in the blood vessels and kidneys, irritability, loss of appetite, constipation, vomiting, muscle hypotonia and impairment of intellectual abilities (Niessen 1996, Goebel 1987).

An infant's **minimum daily requirement** of vitamin D is 400 I.U., corresponding to 10 µg or 0.01 mg of crystalline vitamin D (one I.U. of vitamin D corresponds to 0.025 µg of pure crystalline vitamin D₃).

Premature babies have a higher requirement.

Four options for the prophylaxis of rickets:

Option 1:

Year-round substitution with a daily vitamin D tablet containing 500 I.U. (1000 I.U. for premature babies) is the most reliable method of preventing rickets. The vitamin D is given over the course of a year. Should the child's first birthday fall in the winter, then treatment should be continued until the spring. Babies will be given one Vigantoletten® 500 tablet every day from the start of the second week following their birth, preferably before a breastfeed or bottle feed (combination preparations such as D-Fluoretten®, Fluor-Vigantoletten® or Zymafluor DR®, see p. 260). The tablets disperse quickly in a spoonful of

water and can be drunk easily from the spoon. Since vitamin D deficiency scarcely features in the first few weeks of life, some pediatricians recommend only starting treatment in the 4th week of life in order to allow the baby's digestive system to develop.

Option 2:

Children are given a daily dose of 500 I.U. of vitamin D in the winter only (October-March). Where babies spend two hours a day in natural daylight in the summer period, either no vitamin D is given or a reduced dose, for example half a tablet (250 I.U.) each day or a whole tablet every other day.

Option 3

In the case of children who are susceptible to allergies, or where increased bloating is experienced after taking the tablets, **Vigantol® oil** (1 drop contains 500 I.U.) can also be recommended instead of tablets in both of the options outlined above. The oil has proved to be successful over many years and contains only one excipient as a vehicle for the fat-soluble vitamin D, namely medium-chain triglycerides (vegetable oil). The customary Vigantoletten® contain eleven excipients, namely silicon dioxide, cornstarch, sodium carboxy methyl starch, talc, glycerol tristearate, cellulose, D-mannitol, gelatin, sucrose, partially-hydrated soybean oil and α -tocopherol. Unfortunately, there are no recommended tablets containing fewer excipients. Virgosan® 500 contains lactose (milk sugar), Vitamin D₃-Hevert® is only available in a strength of 1000 I.U. per tablet ('Rote Liste' drug compendium 2001). I consider the long list of additives in the tablets to be worrying for familial allergies and would recommend vitamin D oil instead.

Vigantol® oil is a prescription-only medicine, as there is a risk of an overdose if it is not used properly. Before asking their pediatrician for a prescription, parents must be given full details of the benefits and drawbacks of the oil, and also of its use; if this is not done, their pediatrician will refuse to prescribe the oil for fear of incorrect dosage.

Use of the oil is simple: 1 drop of Vigantol® oil is given to the baby to be licked off from the tip of a spoon once a day before a breastfeed or a meal. Under no circumstances should it be put directly in the baby's mouth! Should 2 drops fall onto the spoon, the spoon should be washed and the process started again. In my experience, skeptical parents are more likely to be accepting of administering drops on a daily basis than a daily dose of tablets. I have also now been able to convince some pediatricians of the advantages of the oil.

Option 4:

In anthroposophic medicine, prophylactic administration of synthetically produced vitamin D is regarded as problematic, owing, inter alia, to the potential impact on the child's mental development "in the sense of early intellectualization and failing to develop thoughts independently" (Goebel 1987). For this reason, **endogenous synthesis of vitamin D** should be primarily promoted; a general, artificial substitute is opposed. With the appropriate lifestyle (the child needs to sit by an open window, on the balcony or outside with his/her

head uncovered for 2 hours each day), there is no need to administer vitamin D, provided that the child is checked every four weeks for symptoms of rickets. Where daylight is in short supply, daily sunlamp treatment can be used to increase the child's vitamin D synthesis. The naked child is held in its mother's arm or on her lap and is exposed to UV light for 30 seconds on his/her abdomen and back, slowly increasing to a maximum of 2 minutes on each side. Caution: babies and mothers must always wear eye protection! In the event of erythema, reduce the time! (Goebel 1987).

Maternal vitamin D intake: Many mothers ask whether they can take vitamin D themselves and pass it onto their babies via breastmilk. Although where mothers take Vigantol® vitamin D and its by-products pass into breastmilk ("Rote Liste" 2001), unfortunately no recommendation exists in this respect, because research has not been carried out into the exact quantity.

Industrially produced infant nutrition almost always contains a vitamin D supplement, meaning that the minimum daily requirement of 400 I.U. (10 µg of crystalline vitamin D₃) is met in part by supplementing infant food. Although some authors (Gahr 1994, Illing 1998) consider double administration to be harmless, when parents ask me about this I recommend calculating the daily vitamin D amount in infant food based on the package label and amount of daily drink and reducing the prophylaxis accordingly, so that their child receives a maximum dose of 500 I.U. of vitamin D each day, because "more doesn't always mean better", and it is better to avoid an overdose.

? Do newborn babies need to take daily fluoride tablets?

No, since from a dental perspective no fluoridization measures to prevent tooth decay are required before the age of six months.

Tooth decay is not caused by a fluoride deficiency, and so taking fluoride tablets before the first milk teeth have erupted is not effective (German Society for Dental and Oral Medicine, DGZMK March 2000).

The combination preparations containing vitamin D and fluoride (D-Fluorctten®, Fluor-Vigantolekten® or Zymafluor DR®) for the prophylaxis of rickets and tooth decay which have been recommended by dentists and pediatricians for years now can no longer be recommended on the basis of current scientific knowledge.

Several studies have shown that fluoride primarily works to inhibit tooth decay through direct contact with the surface of the tooth. For this reason, when using fluorides, local application (toothpaste) takes precedence over the systemic route (tablets). In recent years, in the Scandinavian countries and in the USA and Canada, for example, fluoride tablets have only

been recommended for children who are at risk of tooth decay (children with severe dental caries) and in most cases only starting from the age of three.

The cornerstone of effective prophylaxis of tooth decay:

- A balanced diet (preferably no sugar or white flour products, or only small quantities thereof)
- Daily brushing of teeth (twice a day from the age of three)
- Use of fluorides (primarily through increasing the fluoride concentration in the region of the surface of the teeth).

It is only once the milk teeth have erupted (at 6-7 months) that the hardness of the tooth enamel can be improved by a local increase in fluoride ion concentration on the enamel. Dentists therefore recommend brushing children's teeth daily using a small, soft-bristled toothbrush and no bigger than a pea-sized amount of fluoride-containing children's toothpaste. In order to discourage children from swallowing any toothpaste, children's toothpastes should not be fruit or candy flavored.

Different recommendations: Unfortunately, many pediatricians do not agree with the DGZMK's dental recommendation, continuing to prescribe a daily dose of 0.25 mg of fluoride combined with 500 I.U. of vitamin D to infants from the age of ten days. Although they acknowledge that the proven lack of benefit of the administration of fluoride in the first year of life is scientifically correct, they continue to adhere to the old recommendation. According to the German Society for Pediatrics, the use of vitamin D preparations is an unnecessary complication for prophylactic prescriptions. This behavior is difficult to explain, as the tablets for the prophylaxis of rickets and tooth decay are prescribed by pediatricians, and vitamin D can be prescribed without fluoride substitution without any problems (see above).

It is absurd to prescribe unnecessary fluoride to infants for six months! The halogen fluoride is a highly effective cytotoxin, which is lethal in amounts of 5-15 g (Daudeker 1995, Lewin 1992). A **fluoride overdose** can lead to dental fluorosis, which manifests itself as whitish or brown marks on the enamel of the permanent teeth. Some of the regularly ingested fluoride is stored in the bones. As it suppresses calcium phosphate, particularly in the growth core, daily fluoride intake can be the cause of a constricted jaw and premature aging of the bones in the second half of life. Other side effects can be: poor concentration, forgetfulness, parathyroid hypofunction, porosity of the bones resulting in extreme bone damage (Daudeker 1995, Barmer Lexikon Gesundheit und Medizin).

When providing advice to parents, midwives and pediatricians are caught in the middle of the different recommendations. In light of the evidence-based guidelines of the DGZMK, I am no longer able to recommend fluoride tablets to prevent tooth decay. When it comes to

post-partum care, I will inform parents of the current scientific knowledge and the disagreement among dental and pediatric associations; it will then be up to parents to make the decision.



Translation of **ablecken** – German–English dictionary



ablecken

verb

[infinitive] /'apleken/

Add to word list

[transitive] Löffel

seine Zunge über etw. gleiten lassen

to lick off

- *Sie leckte sich die Finger ab.*
She licked her fingers.
- *Der Hund leckte ihre Hand ab.*

+

[transitive] Blut, Schmutz

mit der Zunge entfernen

to lick off

- *Das Kind leckte zuerst die Schokolade vom Keks ab.*
The child licked the chocolate off the cookie first.

+

[reflexive] Hund, Katze

sein Fell mit der Zunge reinigen

to lick

- *Das Tier leckte sich stundenlang ab.*
The animal licked its fur for hours

Contents

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<https://dictionary.cambridge.org/dictionary/german-english/ablecken>

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Browse

Ablassen von Luft

Ablauf

ablaufen

Ableben

ablecken

ablegen

Ableger

ablehnen

ablehnend

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WORD OF THE DAY

buddy

UK /ˈbʌd.i/ US /ˈbʌd.i/

a friend

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that Patent Owners Exhibits 2023-2066 are being served on February 8, 2024, by filing Patent Owners Exhibits 2023-2066 through the Patent Trial and Appeal Case Tracking System (P-TACTS) and by electronic mail as directed by Petitioner upon the following counsel of record for Petitioners:

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