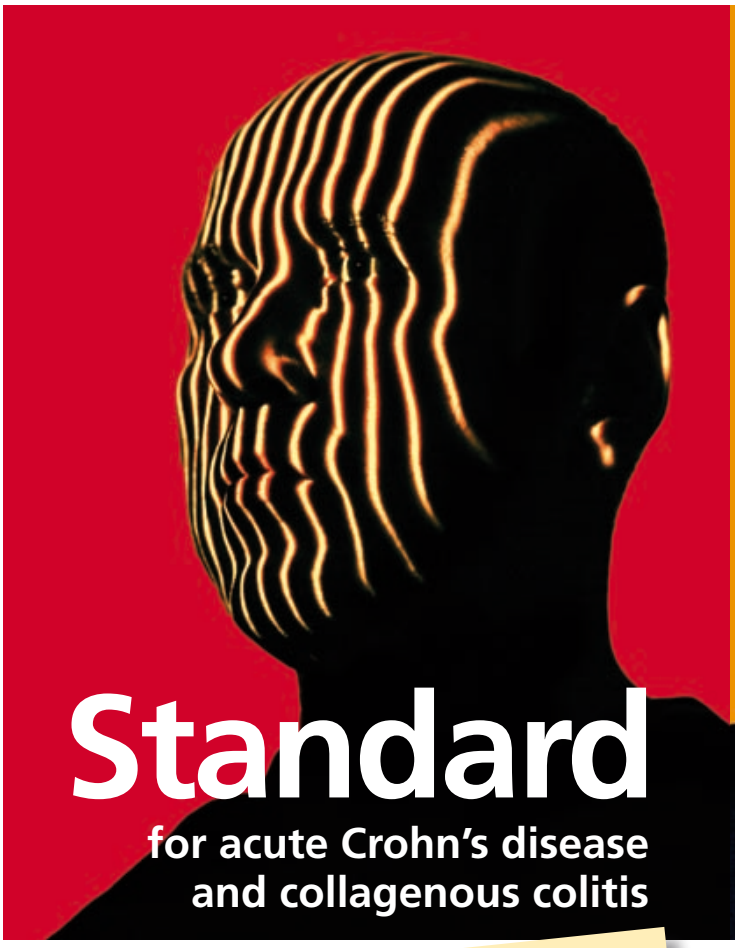
Budesonide

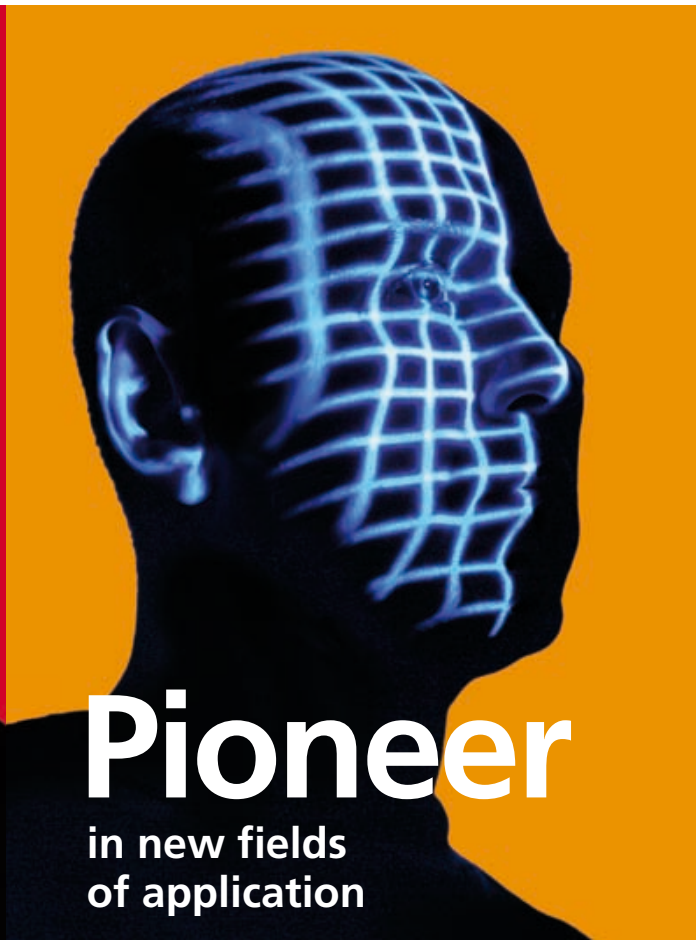
Budenofalk® 3mg

First-line-corticosteroid



Standard

for acute Crohn's disease and collagenous colitis



Pioneer

in new fields of application

+++ Recommended in +++ Guidelines as first line in active ileocoecal Crohn's disease*)

The effect of topical corticosteroids will show in the future therapeutic potential for other intestinal and hepatic diseases. International trials are currently ongoing.

Dr. Falk Pharma **Ex. 1027**
IPR Petition USP 11,246,828

High topical efficacy

Less systemic side effects

Budenofalk® 3mg capsules; Budenofalk® Rectal Foam. Active ingredient: budesonide. **Composition:** 1 gastro-resistant hard capsule of Budenofalk® 3mg (= hard capsule with gastro-resistant pellets) contains: active ingredient: 3 mg budesonide. Other ingredients: povidone K25, lactose monohydrate, sucrose, talc, maize starch, methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), ammonio methacrylate copolymer (type B), ammonio methacrylate copolymer (type A) (= Eudragit L, S, RS and RL), triethyl citrate, titanium dioxide (E171), purified water, gelatin, erythrosine (E127), iron(II,III) oxide (E172), iron(III) oxide (E172), sodium laurilsulphate. Each actuation of Budenofalk® Rectal Foam contains: active ingredient: 2 mg budesonide. Other ingredients: cetyl alcohol, cetostearyl alcohol, polysorbate 60, purified water, sodium edetate, macrogolstearylether (10), propylene glycol, citric acid monohydrate, propellant gases: butane, 2-methylpropane, propane. **Indications:** Budenofalk® 3mg capsules: Mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon. Collagenous colitis. Budenofalk® Rectal Foam: For the treatment of active ulcerative colitis limited to the rectum and the sigmoid colon. **Contraindications:** hypersensitivity to budesonide or any of the other ingredients. Local infections of the intestine (bacteria, fungi, amoebae, viruses). Hepatic cirrhosis and signs of portal hypertension, e.g. in the late stage of primary biliary cirrhosis. Severe hepatic dysfunction. Pregnancy. Lactation. Not to be given to children. Close medical supervision is required in the following diseases: tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer (gastric or duodenal), glaucoma, cataract, family history of diabetes or glaucoma. Chickenpox and measles. Caution should be exercised in patients with slight to moderate hepatic impairment. Additionally capsules: hereditary problems of galactose intolerance, fructose intolerance, the Lapp lactase deficiency, sucrase isomaltase insufficiency, glucose galactose malabsorption. **Side effects:** Oedema of legs, Cushing's syndrome. Pseudotumor cerebri possibly also with oedema of the optic disk in adolescents. Diffuse muscle pain and weakness, osteoporosis. Side effects typical of systemic glucocorticosteroids may occur (the risk of side effects from Budenofalk® is generally lower): Interference with the immune response. Cushing's syndrome: moon-face, truncal obesity, reduced glucose tolerance, diabetes mellitus, sodium retention with oedema formation, increased excretion of potassium, inactivity and/or atrophy of the adrenal cortex, growth retardation in children, disturbance of sex hormone secretion (e.g. amenorrhoea, hirsutism, impotence). Depression, irritability, euphoria, glaucoma, cataract, hypertension, increased risk of thrombosis, vasculitis, stomach complaints, duodenal ulcer, pancreatitis, allergic exanthema, red striae, petechiae, ecchymosis, steroid acne, delayed wound healing, contact dermatitis, aseptic necrosis of bone. Additionally Rectal Foam: urinary tract infections, anaemia, increase in erythrocyte sedimentation rate, leukocytosis, increased appetite, insomnia, headache, dizziness, disturbances of smell, hypertension, nausea, abdominal pain, dyspepsia, flatulence, paraesthesias in the abdominal region, anal fissure, aphthous stomatitis, frequent urge to defecate, haemorrhoids, rectal bleeding, increase in transaminases (GOT, GPT), increase in parameters of cholestasis (GGT, AP), acne, increased sweating, increase in amylase, change in cortisol, burning in the rectum and pain, asthenia, increase in body weight. **Interactions and dosage:** see patient information. Available on prescription only. Date of information: 4/2007

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***) DGVS Guidelines:** *Hoffmann JC et al. Z Gastroenterol. 2008;46(9):1094-1146.* **ECCO Guidelines:** *Travis SPL et al. Gut. 2006;55(Suppl.1):i16-i35.* **AGA Guidelines:** *Lichtenstein GR et al. Gastroenterology. 2006;130(3):935-9.*