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LABEL: STELARA- ustekinumab injection, solution

STELARA- ustekinumab solution

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NDC Code(s): 57894-054-16, 57894-054-27, 57894-060-02, 57894-060-03, [view more](#)

Packager: Janssen Biotech, Inc.

Category: HUMAN PRESCRIPTION DRUG LABEL

DEA Schedule: None

Marketing Status: Biologic Licensing Application

DRUG LABEL INFORMATION

Updated December 16, 2020

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use STELARA® safely and effectively. See full prescribing information for STELARA®. STELARA® (ustekinumab) injection, for subcutaneous ...
- +

TABLE OF CONTENTS

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1 INDICATIONS AND USAGE

1.1 Psoriasis (Ps) STELARA® is indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic ...
- +

2 DOSAGE AND ADMINISTRATION

2.1 Psoriasis - Subcutaneous Adult Dosage Regimen - For patients weighing 100 kg or less, the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks. For ...
- +

3 DOSAGE FORMS AND STRENGTHS

STELARA® (ustekinumab) is a colorless to light yellow solution and may contain a few small translucent or white particles. Subcutaneous Injection - Injection: 45 mg/0.5 mL or 90 mg/mL solution ...
- +

4 CONTRAINDICATIONS

STELARA® is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients [see Warnings and Precautions (5.5)].
- +

5 WARNINGS AND PRECAUTIONS

5.1 Infections - STELARA® may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients ...
- +

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the label: Infections [see Warnings and Precautions (5.1)] Malignancies [see Warnings and Precautions (5.4)] Hypersensitivity ...
- +

7 DRUG INTERACTIONS

7.1 Concomitant Therapies - In psoriasis studies the safety of STELARA® in combination with immunosuppressive agents or phototherapy has not been evaluated [see Warnings and Precautions (5.8)] ...
- +

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy - Risk Summary - Limited data on the use of STELARA® in pregnant women are insufficient to inform a drug associated risk [see Data]. In animal reproductive and developmental ...
- +

10 OVERDOSAGE

Single doses up to 6 mg/kg intravenously have been administered in clinical studies without dose-limiting toxicity. In case of overdosage, it is recommended that the patient be monitored for any ...
- +

11 DESCRIPTION

Ustekinumab, a human IgG1K monoclonal antibody, is a human interleukin-12 and -23 antagonist. Using DNA recombinant technology, ustekinumab is produced in a murine cell line (Sp2/O). The ...
- +

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action - Ustekinumab is a human IgG1K monoclonal antibody that binds with specificity to the p40 protein subunit used by both the IL-12 and IL-23 cytokines. IL-12 and IL-23 are ...
- +

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility - Animal studies have not been conducted to evaluate the carcinogenic or mutagenic potential of STELARA®. Published literature showed ...
- +

14 CLINICAL STUDIES

14.1 Psoriasis - Two multicenter, randomized, double-blind, placebo-controlled studies (Ps STUDY 1 and Ps STUDY 2) enrolled a total of 1996 subjects 18 years of age and older with plaque ...
- +

15 REFERENCES

1 - Surveillance, Epidemiology, and End Results (SEER) Program ([www.seer.cancer.gov](#)) SEER*Stat Database: Incidence - SEER 6.6.2 Regs Research Data, Nov 2009 Sub (1973–2007) - Linked To County ...
- +

16 HOW SUPPLIED/STORAGE AND HANDLING

STELARA® (ustekinumab) injection is a sterile, preservative-free, colorless to light yellow solution and may contain a few small translucent or white particles. It is supplied as individually ...
- +

17 PATIENT COUNSELING INFORMATION

Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide and Instructions for Use). Infections - Inform patients that STELARA® may lower the ability of ...
- +

SPL UNCLASSIFIED SECTION

Prefilled Syringe Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403 and at Cilag AG, Schaffhausen ...
- +

MEDICATION GUIDE

This Medication Guide has been approved by the U.S. Food and Drug AdministrationRevised: 12/2020 MEDICATION GUIDE - STELARA® (stel ar' a) (ustekinumab) injection, for ...
- +

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE - STELARA (stel ar' a) (ustekinumab) injection, for subcutaneous use - Instructions for injecting STELARA using a prefilled syringe. Read this Instructions for Use before you ...
- +

INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE - STELARA (stel ar' a) (ustekinumab) injection, for subcutaneous use - Instructions for injecting STELARA from a vial. Read this Instructions for Use before you start using ...
- +

PRINCIPAL DISPLAY PANEL - 45 MG/0.5 ML VIAL CARTON

Stelara® (ustekinumab) Injection - 45 mg/0.5 mL - For subcutaneous use - Contains one 45 mg/0.5 mL syringe - NDC 57894-060-03 - Single-dose prefilled syringe - Discard unused portion - The 45 mg ...
- +

PRINCIPAL DISPLAY PANEL - 90 MG/ML SYRINGE CARTON

Stelara® (ustekinumab) Injection - 90 mg/mL - For subcutaneous use - Contains one 90 mg/mL syringe - NDC 57894-061-03 - Single-dose prefilled syringe - Discard unused portion - The 90 mg prefilled ...
- +

PRINCIPAL DISPLAY PANEL - 130 MG/26 ML VIAL CARTON

NDC 57894-054-27 - Single-Dose vial - Discard unused portion - Stelara® (ustekinumab) Injection - 130 mg/26 mL - (5 mg/mL) For Intravenous Infusion Only - Must be diluted - ATTENTION: Dispense - the ...
- +

INGREDIENTS AND APPEARANCE

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