



ALL DRUGS

HUMAN DRUGS

ANIMAL DRUGS

MORE WAYS TO SEARCH

Enter drug, NDC code, drug class, or Set ID



HOME

+ NEWS

FDA RESOURCES

+ NLM SPL RESOURCES

+ APPLICATION DEVELOPMENT SUPPORT

HELP

LABEL: STELARA- ustekinumab injection, solution

STELARA- ustekinumab solution

LABEL RSS

SHARE

f

i

+

VIEW PACKAGE PHOTOS



VIEW MORE

SAFETY

Report Adverse Events

FDA Safety Recalls

Presence in Breast Milk

RELATED RESOURCES

Medline Plus

Clinical Trials

+ PubMed

Biochemical Data Summary

MORE INFO FOR THIS DRUG

View Labeling Archives

RxNorm

Get Label RSS Feed

View NDC Code(s) NEW!

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

If you are a consumer or patient please visit [this version](#).

DOWNLOAD DRUG LABEL INFO: [PDF](#) | [XML](#) | [B](#)

MEDICATION GUIDE: [HTML](#) | [1](#)

OFFICIAL LABEL (PRINTER FRIENDLY) [P](#)

VIEW ALL SECTIONS

- + 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
- Table of Contents
- + 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
- Product Information

VIEW ALL SECTIONS

FIND ADDITIONAL RESOURCES (also available in the [left menu](#))

SAFETY

[Report Adverse Events](#), [FDA Safety Recalls](#), [Presence in Breast Milk](#)

RELATED RESOURCES

[Medline Plus](#), [Clinical Trials](#), [PubMed](#), [Biochemical Data Summary](#)

MORE INFO ON THIS DRUG

[View Labeling Archives](#), [RxNorm](#), [Get Label RSS Feed](#), [View NDC Code\(s\)](#) NEW!



About DailyMed

Customer Support

Copyright

Privacy

Web Accessibility

National Institutes of Health

U.S. National Library of Medicine

Health & Human Services