

Medication Guide

ILUMYA® (e-LOOM-me-a)
(tildrakizumab-asmn)

injection, for subcutaneous use

What is the most important information I should know about ILUMYA?

ILUMYA may cause serious side effects, including:

Serious allergic reactions. Get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:

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|---|---|
| <ul style="list-style-type: none">• feel faint | <ul style="list-style-type: none">• skin rash |
| <ul style="list-style-type: none">• swelling of your face, eyelids, lips, mouth, tongue or throat | <ul style="list-style-type: none">• trouble breathing or throat tightness |
| | <ul style="list-style-type: none">• chest tightness |

Infections. ILUMYA is a medicine that may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with ILUMYA and may treat you for TB before you begin treatment with ILUMYA if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with ILUMYA.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

| | | |
|--|---|--|
| <ul style="list-style-type: none">• fever, sweats, or chills• cough• shortness of breath | <ul style="list-style-type: none">• warm, red, or painful skin or sores on your body different from your psoriasis• weight loss• diarrhea or stomach pain | <ul style="list-style-type: none">• burning when you urinate or urinating more often than normal |
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See **“What are the possible side effects of ILUMYA?”** for more information about side effects.

What is ILUMYA?

ILUMYA is a prescription medicine used to treat adults with moderate to severe plaque psoriasis who may benefit from taking injections, pills (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).

It is not known if ILUMYA is safe and effective in children under 18 years of age.

Do not use ILUMYA if you have had a severe allergic reaction to tildrakizumab or any of the other ingredients in ILUMYA. See the end of this Medication Guide for a complete list of ingredients in ILUMYA.

Before receiving ILUMYA, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **“What is the most important information I should know about ILUMYA?”**
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- recently received or are scheduled to receive a vaccine (immunization). You should avoid receiving live vaccines during treatment with ILUMYA.
- are pregnant or plan to become pregnant. It is not known if ILUMYA can harm your unborn baby.
 - o If you become pregnant during treatment with ILUMYA, you are encouraged to enroll in the pregnancy registry. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider or call 1-866-626-6847 to enroll in this registry or visit

<https://mothertobaby.org/ongoing-study/ilumya-tildrakizumab-asmn>.

- are breastfeeding or plan to breastfeed. It is not known if ILUMYA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive ILUMYA?

- ILUMYA should only be given to you by a healthcare provider.
- ILUMYA is given as an injection under your skin (subcutaneous injection) in areas of your body such as your thighs, stomach area (abdomen), or upper arm.
- If you miss a follow-up appointment and do not receive your dose of ILUMYA, schedule another appointment as soon as possible.

What are the possible side effects of ILUMYA?

ILUMYA may cause serious side effects. See “What is the most important information I should know about ILUMYA?”

The most common side effects of ILUMYA include:

- upper respiratory infections
- injection site reactions
- diarrhea

These are not all of the possible side effects of ILUMYA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of ILUMYA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider for information about ILUMYA that is written for health professionals.

What are the ingredients in ILUMYA?

Active ingredient: tildrakizumab-asmn

Inactive ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and Water for Injection, USP.

Manufactured by: **Sun Pharmaceutical Industries Limited** Mumbai, Maharashtra India 400 063

U.S. License No. 2092

U.S. Patent No. 8,404,813; 8,293,883 and 9,809,648

Tildrakizumab-asmn (active ingred.) Product of South Korea.

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