

ILUMYA

Tildrakizumab Solution for Injection 100 mg/ml

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What ILUMYA is used for

ILUMYA is used to treat a skin condition called plaque psoriasis in adults with moderate to severe disease who are candidates for injections, pills (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).

Plaque psoriasis causes inflammation of the skin. ILUMYA reduces the inflammation and other symptoms of the disease, and promotes skin clearance.

ILUMYA has not been studied in patients under 18 years of age.

ILUMYA may be used in elderly patients aged 65 years and over.

How ILUMYA works

ILUMYA contains the active substance tildrakizumab.

Tildrakizumab belongs to a group of medicines called interleukin (IL) inhibitors.

This medicine works by blocking the activity of a protein called IL-23, a substance found in the body which is involved in normal inflammatory and immune responses and which is present at increased levels in diseases such as psoriasis.

If you have any questions about how ILUMYA works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

Before you use ILUMYA

Tell your doctor if you have any of the conditions mentioned below or if you have ever experienced any of these conditions.

When you must not use it

- If you have had a severe allergic reaction to tildrakizumab or any of the other ingredients in ILUMYA. See the end of this document for a complete list of ingredients in ILUMYA.

Before you start to use it

Tell your doctor if you:

- experience allergic reactions with symptoms such as chest tightness, wheezing, swelling of the face, lips or throat and itchy rash do not inject more ILUMYA and contact your doctor immediately.
- have an infection that does not go away or that keeps coming back
- have tuberculosis (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.

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to have a baby.

The effects of ILUMYA in pregnancy are unknown. It is preferable to avoid the use of ILUMYA in pregnancy.

If you are a woman of childbearing potential, you are advised to avoid becoming pregnant.

Talk to your doctor about the benefits to you using ILUMYA verses the potential risk to your unborn child.

Talk to your doctor if you are breast-feeding or planning to breast-feed.

If you have not told your doctor about any of the above, tell them before you start taking ILUMYA.

Taking other medicines

Avoid use of live vaccines in patients treated with ILUMYA.

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

How to use ILUMYA

ILUMYA may be given to you by your doctor or nurse, or you or a caregiver may be taught how to inject yourself with the medicine.

You and your doctor, nurse or pharmacist should decide if you should inject ILUMYA yourself.

Do not inject yourself if you have not been properly trained by your doctor, nurse or pharmacist. A caregiver may also give you your ILUMYA injection after proper training.

How much to use

The recommended dose of ILUMYA is 100 mg by subcutaneous injection at weeks 0, and 4 and every 12 weeks thereafter.

If your doctor gives you different dosing instructions follow your doctor's instructions.

Instructions for use

Before using the pre-filled syringes: Important points to know

- Before you use ILUMYA pre-filled syringes, read and carefully follow all the step-by-step instructions. Keep the instructions for use and refer to them as needed.
- The pre-filled syringes must not be shaken.

Preparation

1. Take a pack from the refrigerator (if stored in the refrigerator)

- Take a carton pack out of the refrigerator and place the original and unopened carton pack on a clean and flat working surface.

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2. Wait for 30 minutes (if stored in the refrigerator)

- Leave the pre-filled syringe in the ILUMYA carton (with the lid closed) and let it sit at room temperature for 30 minutes.



3. Inspect the medicine

- Remove the pre-filled syringe from the carton when ready to inject.
 - Check the expiration date on the carton and pre-filled syringe and discard if the date has passed.
 - DO NOT pull off the needle cover until you are ready to inject.
- Inspect ILUMYA visually for particulate matter and discoloration prior to administration.
 - ILUMYA is a clear to slightly opalescent and colourless to slightly yellow solution.
 - DO NOT use if the liquid contains visible particles or the syringe is damaged. Air bubbles may be present; there is no need to remove them.
 - DO NOT use the product if it has been dropped on a hard surface or damaged.



4. Collect all the materials you need

- On a clean, well-lit work surface, place the:
 - alcohol wipes
 - cotton ball or gauze pad
 - sticking plaster
 - sharps disposal container

5. Wash your hands

- Wash your hands thoroughly with soap and water.

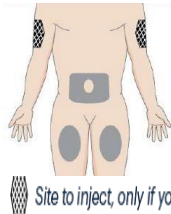


6. Choose an injection site

- Choose an injection site with clear skin and easy access such as abdomen, thighs or upper arm.
 - DO NOT administer 5 cm around the navel or where the skin is tender, bruised, abnormally red, hardened or affected by psoriasis.
 - DO NOT inject into scars, stretch marks, or blood vessels.
 - The upper arm is only suitable when someone else is injecting you.

7. Clean injection site

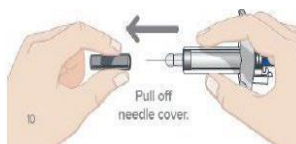
- Clean the injection site with an alcohol wipe and allow the skin to dry.
 - Do not touch this area again before giving the injection.



Site to inject, only if you have someone helping you.

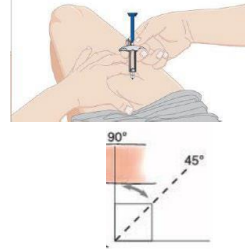
8. Pull off the needle cover

- While holding the body of the pre-filled syringe, remove the needle cover as shown and discard. You may see 1 or 2 drops of liquid and that is okay.
 - DO NOT touch the blue plunger yet.
 - DO NOT use if pre-filled syringe or needle is bent.



9. Pinch skin & insert needle

- Gently pinch your skin at the chosen injection site.
- Insert the entire needle into the pinched skin between your fingers, at a 45 to 90-degree angle.
- DO NOT place your finger on the plunger while inserting the needle.
- Hold the pre-filled syringe steady.



10. Inject

- After inserting the needle, let go of the skin gently.
- Press down the blue plunger until it can go no further. This activates the safety mechanism that will ensure full retraction of the needle after the injection is given.
- A complete dose is administered if the blue plunger cannot go any further, and there are no spills.

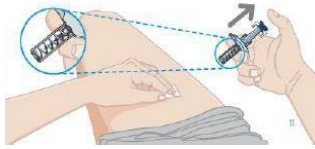


11. Remove the used syringe

- Remove the needle from the skin entirely before letting go of the blue plunger.
 - After the blue plunger is released, the safety lock will draw the needle inside the needle guard.
- Dispose of used syringe in a sharps disposal container right away after use.
- If there is some residual fluid or a tiny bit of blood, clean the injection site with a cotton ball or gauze pad WITHOUT applying any pressure. If you feel the need, you can use a sticky plaster to cover the injection site.

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How long to use it

ILUMYA is for long term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

Do not stop using ILUMYA just because you feel better. It is important that you do not stop unless your doctor tells you to.

It is not dangerous to stop using ILUMYA but if you stop your psoriasis symptoms may come back.

If you forget to use it

If you have forgotten to inject a dose of ILUMYA, inject the next dose as soon as you remember. Then talk to your doctor to discuss when you should inject the next dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you have administered more ILUMYA than you should or the dose has been administered sooner than according to your doctor's prescription, tell your doctor.

Do this even if there are no obvious signs of discomfort or poisoning.

While you are using it

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

Look out for infections and allergic reactions.

ILUMYA can potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are taking ILUMYA.

Stop using ILUMYA and tell your doctor or seek medical help immediately if you notice any signs indicating a possible serious infection or an allergic reaction (see Side effects). If you need to be vaccinated, tell your doctor you are taking ILUMYA before you have the vaccination.

You should not be given a live vaccination while being treated with ILUMYA.

As soon as you start using ILUMYA tell all doctors, dentists and pharmacists who are treating you that you are using ILUMYA.

Remind your doctor or pharmacist you are taking ILUMYA before you start any new medicine.

Tell your doctor if you become pregnant while taking ILUMYA.

Tell your doctor or pharmacists as soon as possible if you do not feel well, you think you have an infection or you have any unwanted side effects.

Things you must not do

Never leave the pre-filled syringe lying around where others might tamper with it.

Do not use this medicine if the liquid contains easily visible particles, is cloudy or is distinctly brown.

Do not use the pre-filled syringe if any of the outer packaging is damaged, the expiry date has passed or the seals are broken.

It may not be safe for you to use. Do not shake the pre-filled syringe.

Do not use the syringe if it is damaged or cap has been removed.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Dispose of the used ILUMYA pre-filled syringe immediately after use in a sharps container.

The ILUMYA pre-filled syringe should never be re-used.

Side effects

Like all medicines, ILUMYA can have side effects, although not everybody gets them.

Serious Side Effects

If any of the following happens, stop using ILUMYA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions which may include symptoms such as feel faint, swelling of your face, eyelids, lips, mouth, tongue or throat, skin rash, trouble breathing or throat tightness, chest tightness.
- Infection or signs of infection such as fever, sweats, or chills, cough, shortness of breath, blood in your phlegm (mucus), muscle aches, warm, red, or painful skin or sores on your body different from your psoriasis, weight loss, diarrhea or stomach pain, burning when you urinate or urinating more often than normal.

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

Other Side Effects Common:

- upper respiratory infections
- injection site reactions
- diarrhea

Other side effects not listed above may

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also occur in some people. Tell your doctor if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ILUMYA

Storage

Store refrigerated at temperatures between 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until the time of use.

Tildrakizumab (Ilumya) can be kept at 25°C (77°F) for up to 30 days or at 30°C (86°F) for up to 3 days in the original carton to protect from light. Once stored at 25°C or 30°C, do not place back in the refrigerator. If not used within 30 days at 25°C or within 3 days at 30°C, discard Tildrakizumab (Ilumya).

Do not freeze. Do not shake.

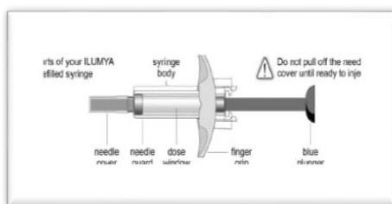
Keep out of reach of children.

Disposal

Dispose of used syringe in a sharps disposal container right away after use.

Product description

ILUMYA solution for injection, for subcutaneous use, is a sterile, preservative-free, clear to slightly opalescent and colorless to slightly yellow solution. ILUMYA is supplied in a single-dose prefilled syringe with a glass barrel and 29-gauge fixed, 1/2-inch needle.



Active ingredient:

Tildrakizumab

Excipients:

L-histidine, L-Histidine hydrochloride monohydrate, Polysorbate 80, sucrose and Water for Injection, USP.

No preservative.

MAL number(s)

MALXXXXXXX

Manufacturer:

Manufactured By:

Vetter Pharma- Fertigung GmbH & Co. KG,
Schutzenstr.87 und 99-101
88212 Ravensburg, Germany

Released by:

Sun Pharmaceutical Industries
(Europe) B.V.
Polarisavenue 87, Hoofddorp, 2132JH
Netherlands

Product Registration Holder:

Ranbaxy (Malaysia) Sdn. Bhd.
(a SUN PHARMA company)
Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah,
Malaysia.

Date of revision

09/09/2024

Serial Number:

NPRA (R3)24/58

Ingredients