

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Ilumya

Solution for injection in pre-filled syringe

Name and quantity of active ingredient:

Each pre-filled syringe contains 100 mg tildrakizumab in 1 mL.

List of inactive ingredients and allergens in this medicine in section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Ilumya is intended to treat plaque psoriasis in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.

Therapeutic group:

immunosuppressants, interleukin inhibitors.

Ilumya 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.

Using Ilumya will benefit you by improving clearance of skin lesions and reducing your symptoms.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to tildrakizumab or any of the other ingredients in this medicine (see section 6)
- you have an infection which your doctor thinks is important, for example, active tuberculosis which is an infectious disease mainly affecting the lungs

Special warnings about using this medicine

Before using this medicine, tell your doctor if:

- you experience allergic reactions with symptoms such as chest tightness, wheezing, swelling of the face, lips or throat; do not inject more Ilumya and contact your doctor immediately
- you currently have an infection or if you have long-term or repeated infections
- you have recently had or plan to have a vaccination

If you are not sure whether any of these conditions apply to you, talk to your doctor, pharmacist or nurse before using Ilumya.

Look out for infections and allergic reactions

Ilumya can 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 section 4, 'Side effects').

Children and adolescents

The safety and efficacy of Ilumya in children and adolescents under 18 years old has not been established yet, so Ilumya is not recommended for use in children and adolescents.

Other medicines and Ilumya

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. These include vaccines and immunosuppressants (medicines that affect the immune system).

You should not be given certain types of vaccines (live vaccines) while using Ilumya. There are no data about using Ilumya and live vaccines concomitantly.

Pregnancy, breastfeeding, and fertility

It is preferable to avoid use of Ilumya during pregnancy. The effects of this medicine in pregnant women are not known.

If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use an effective method of contraception while receiving treatment with Ilumya and for at least 17 weeks after treatment.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Ilumya has no or little effect on the ability to drive and use machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Ilumya is intended for use under the guidance and supervision of a doctor experienced in the diagnosis and treatment of psoriasis.

Only your doctor will determine your dose and how you should take this medicine.

Each syringe is for single use only.

The recommended dose of Ilumya is usually 100 mg by subcutaneous injection on Weeks 0 and 4 and every 12 weeks after that.

Your doctor will decide how long you need to take Ilumya.

After proper training with subcutaneous injection technique, you may inject Ilumya yourself if your doctor determines that it is appropriate.

For instructions on how to inject Ilumya yourself, see 'INSTRUCTIONS FOR USE' at the end of this leaflet.

Talk to your doctor about when you will have your injections and follow-up appointments.

Do not exceed the recommended dose.

If you use too much Ilumya

If you have injected more Ilumya than you should or have been given the dose sooner than required by your doctor's prescription, tell your doctor.

If you forget to use Ilumya

If you have forgotten or missed an Ilumya injection, inject the dose as soon as possible. Then, go back to using the medicine according to your scheduled intervals.

If you stop using Ilumya

The decision to stop using Ilumya should be discussed with your doctor. Your symptoms may return when you stop using it.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects

If you notice any of the following, **contact your doctor immediately**:

- swelling of the face, lips or throat
- breathing difficulties

As these may be signs of an allergic reaction.

Additional side effects

Most of the following side effects are mild. If any side effect becomes severe, tell your doctor or pharmacist.

Very common side effects (may affect more than 1 in 10 users):

- upper respiratory infections

Common side effects (may affect up to 1 in 10 users):

- inflammation of the digestive system (gastroenteritis)
- nausea
- diarrhoea
- pain at the injection site
- back pain
- headache

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Keep the product in the original carton in order to protect from light until the time of use. Do not shake. Store in a refrigerator (2°C - 8°C).

Do not freeze.

After taking the injection pen out of the refrigerator, wait approximately 30 minutes to allow the Ilumya solution in the syringe to reach room temperature (up to 25°C). Do not warm in any other way.

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

Once the pack is taken out of the refrigerator, do not store tildrakizumab above 25°C or return it to the refrigerator. Write down the date of removal from the refrigerator in the space provided on the outer carton. Use the syringe within 30 days after taking it out of the refrigerator or by the expiry date, whichever occurs first.

Do not throw away the medicine via wastewater or household waste. Ask your pharmacist how to throw away this medicine. This will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

sucrose, L-histidine hydrochloride monohydrate, polysorbate 80, L-histidine and water for injections.

What the medicine looks like and contents of the pack

Ilumya is a clear to slightly milky and colourless to slightly yellow solution.

Ilumya is available in packs containing one pre-filled syringe.

Each pre-filled syringe has a needle guard and needle cover.

Manufacturer's name and address: Sun Pharmaceutical Industries Europe B.V.
Avenue 87, 2132 JH Hoofddorp, the Netherlands.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761.

Approved in June 2021.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 167-49-36455.

INSTRUCTIONS FOR USE

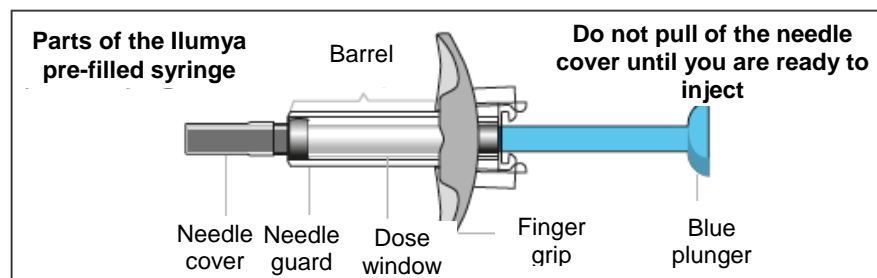
Before using the pre-filled syringes:

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.
- Do not shake the pre-filled syringes.
- Read the Ilumya package leaflet to learn more about your medicine.

PRODUCT DESCRIPTION

This is what the Ilumya pre-filled syringe looks like:



Prepare

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.

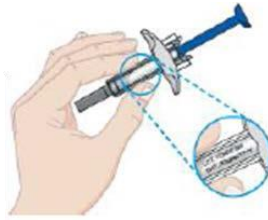


2. Wait 30 minutes (if stored in the refrigerator)

- 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 you are ready to inject.
 - Check the expiration date on the carton and pre-filled syringe and discard the syringe 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 before injection.
 - Ilumya is a clear to slightly milky 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.**



4. Collect all the materials you need

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

5. Wash your hands

- Wash your hands thoroughly with soap and water.

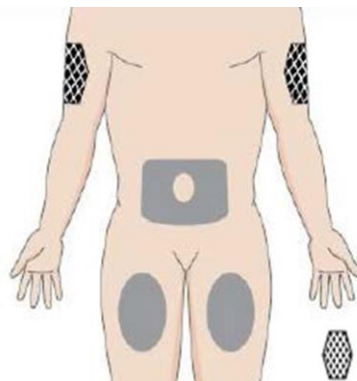


6. Choose an injection site

- Choose an injection site in which the **skin is clear** and easy to access such as the **abdomen, thighs or upper arm**.
 - DO NOT administer within 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.
 - o Do not touch this area again before giving the injection.



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

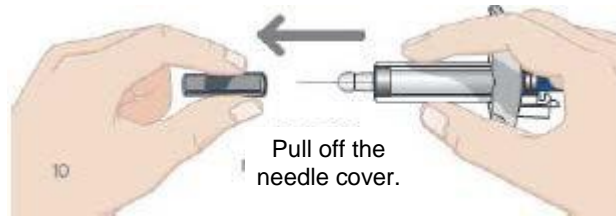
INJECTION

8. Remove the needle cover

- While holding the body of the pre-filled syringe, remove the needle cover as shown in

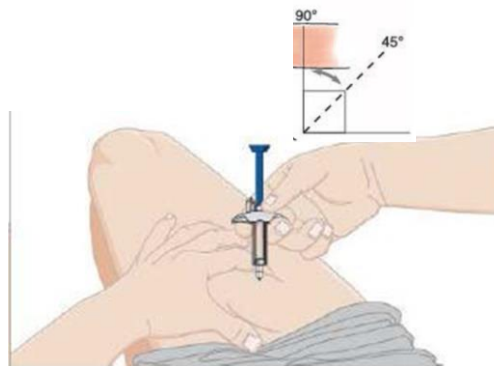
the figure and discard it. You may see one or two drops of liquid. This is normal.

- DO NOT touch the blue plunger yet.
- DO NOT use if the pre-filled syringe or needle is bent.



9. Pinch skin and insert needle

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



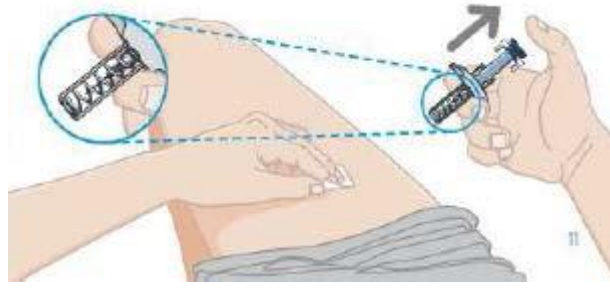
10. INJECT

- 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 the used syringe in a sharps disposal container after use.
- If there is some residual fluid or a little 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 sticking plaster to cover the injection site.