

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.

Inactive ingredients and allergens in this medicine: see 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.

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).

Special warnings about using this medicine

Before using ILUMYA, tell your doctor if:

- you have an infection that does not go away or that keeps coming back.
- you have tuberculosis (TB) or have been in close contact with someone with TB.
- you have recently had or plan to have a vaccination. You should avoid receiving live-attenuated vaccines during treatment with ILUMYA. No data are available about using ILUMYA together with live-attenuated or inactive vaccines.

ILUMYA is a medicine that lowers the ability of your immune system to fight infections and may increase the risk of infections. Your doctor will monitor you carefully for signs and symptoms of TB and infections before starting ILUMYA treatment, and during and after ILUMYA treatment.

Stop treatment and contact your doctor immediately if you have an infection or symptoms of an infection (see section 4, under 'Serious side effects').

ILUMYA can cause serious allergic reactions.

Seek urgent medical help immediately if you notice signs indicating a serious allergic reaction (see section 4, under 'Serious side effects').

It is important to write down the date and the batch number (shown on the pack after Lot)

every time you get a new pack of ILUMYA, and keep the information in a safe place.

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.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking dextromethorphan, a cough medicine. When it is used with ILUMYA, the concentration of dextromethorphan in your blood increases.

Pregnancy and breastfeeding

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

Pregnancy

It is not known if this medicine can harm your unborn baby.

Breastfeeding

If you are breastfeeding or plan to breastfeed ask your doctor for advice before using this medicine.

It is not known if ILUMYA passes into your breast milk.

Important information about some of this medicine's ingredients

Each prefilled syringe of ILUMYA 100 mg contains 0.5 mg polysorbate 80, which is equivalent to 0.5 mg in 1 ml.

This medicine can cause sensitivity in patients who are sensitive to polysorbates. Tell your doctor if you have any known allergy.

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 prescribed by your doctor, 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 ILUMYA 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**:

- feeling faint
- swelling of the face, eyelids, lips, mouth, tongue, or throat
- rash
- breathing difficulties or throat tightness
- chest tightness

as these may be signs of a serious allergic reaction.

Contact your doctor right away if you notice any of the following reactions:

- 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 sensation when you urinate or urinating more often than normal

because these could be signs of an infection.

Most common side effects:

- upper respiratory infections
- injection site reactions

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

- inflammation of the digestive system (gastroenteritis)
- nausea

- diarrhea
- 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 your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package and syringe label. 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. Do not shake. Store in a refrigerator (2°C - 8°C).

Do not freeze.

After taking a pre-filled syringe 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 it above 25°C or return it to the refrigerator. Write down the date of removal from the refrigerator in the space provided on the 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 colorless 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.

Polaris Avenue 87, 2132 JH Hoofddorp, The Netherlands.

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

Revised in December 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 167-49-36455-00.

למידע נוסף על התכשיר ולעלונים מעודכנים בשפות עברית, ערבית ואנגלית סירקו את הקוד הבא:
For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the code:



<https://israel drugs.health.gov.il/#!/medDetails/167%2049%2036455%2000>

ניתן לפנות לבעל הרישום של התכשיר בבקשה לקבל עלון מודפס לצרכן בשפה האנגלית בכתובת הדואר האלקטרוני Info@taro.com או בטלפון מספר 1-800-464-664.

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.

INSTRUCTIONS FOR USE

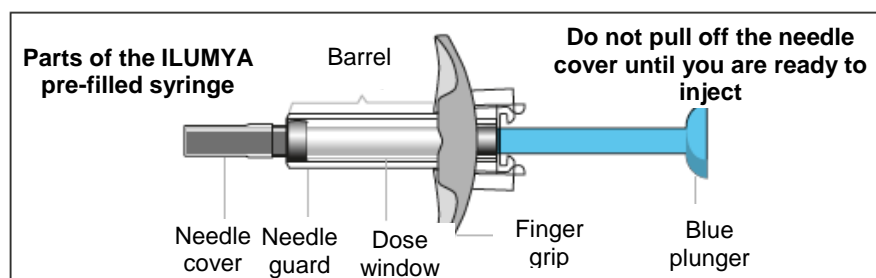
Before using the pre-filled syringes:

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 patient leaflet to learn more about your medicine.

PRODUCT DESCRIPTION

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



Prepare

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

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

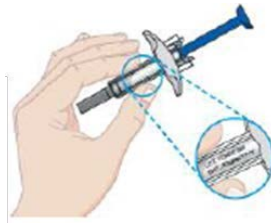
2. Wait 30 minutes (if stored in the refrigerator)

- Leave the pre-filled syringe in the 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 colorless 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 medicine if it was dropped on a hard surface or is damaged.



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.

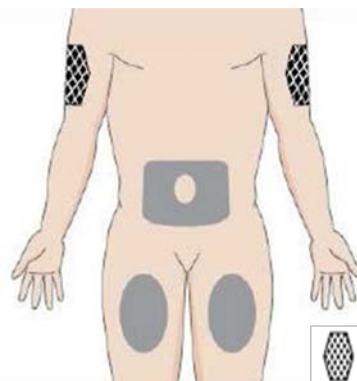



6. Choose an injection site

- 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.
 - Alternate injection sites for every administration.

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.

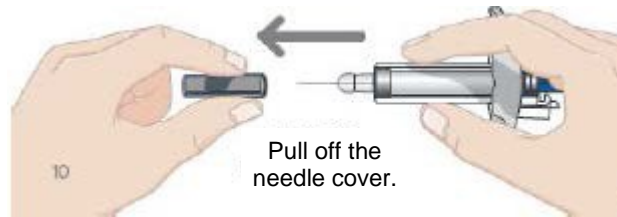


 Site to inject, only if you have someone helping you.

INJECTION

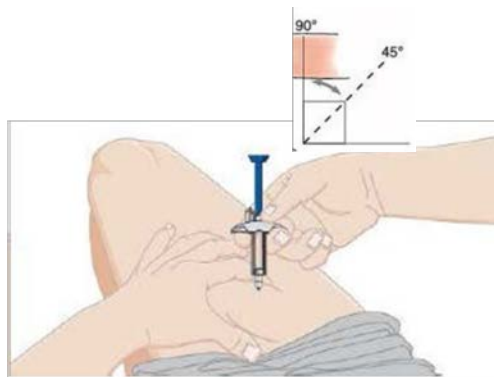
8. Remove the needle cover

- 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 **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.



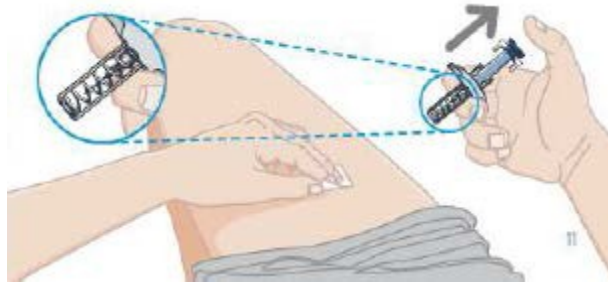
10. Inject

- 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 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.