

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Ilumetri 100 mg solution for injection in pre-filled syringe tildrakizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ilumetri is and what it is used for
2. What you need to know before you use Ilumetri
3. How to use Ilumetri
4. Possible side effects
5. How to store Ilumetri
6. Contents of the pack and other information

1. What Ilumetri is and what it is used for

Ilumetri 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.

Ilumetri is used to treat a skin condition called plaque psoriasis, in adults with moderate to severe disease. Using Ilumetri will benefit you by improvements of skin clearance and reducing your symptoms.

2. What you need to know before you use Ilumetri

Do not use Ilumetri:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ilumetri:

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

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using Ilumetri.

Look out for infections and allergic reactions

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

Stop using Ilumetri and tell your doctor or seek medical help immediately if you notice any signs indicating a possible serious infection or an allergic reaction (see 4. Possible side effects).

Children and adolescents

Ilumetri is not recommended for use in children and adolescents under 18 years of age. This is because it has not yet been evaluated in this group of patients.

Other medicines and Ilumetri

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. These include vaccines and immunosuppressants (medicines that affect the immune system).

You should not be given certain types of vaccines (live vaccines) while using Ilumetri. No data are available with the concomitant use of Ilumetri and live vaccines.

Pregnancy, breastfeeding and fertility

It is preferable to avoid the use of Ilumetri in 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 whilst having treatment with Ilumetri and for at least 17 weeks after treatment.

If you are pregnant or breast-feeding, 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

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

3. How to use Ilumetri

Ilumetri is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. This medicine is for single use only.

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

In patients with certain characteristics (e.g. high disease burden, body weight \geq 90 kg) 200 mg may provide greater efficacy.

Your doctor will decide for how long you need to take Ilumetri.

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

For instructions on how to inject Ilumetri 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.

Use in children and adolescents

The safety and efficacy of Ilumetri in children and adolescents under 18 years of age has not yet been established and therefore Ilumetri is not recommended for use in children or adolescents.

If you use more Ilumetri than you should

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

If you forget to use Ilumetri

If you have forgotten or missed an Ilumetri injection, administer the dose as soon as possible. Thereafter, resume dosing at the regularly scheduled interval.

If you stop using Ilumetri

The decision to stop using Ilumetri should be discussed with your doctor. Your symptoms may return upon discontinuation.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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.

Other side effects

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

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

- Upper respiratory infections

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

- Gastroenteritis
- Nausea
- Diarrhoea
- Injection site pain
- Back pain
- Headache

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [The Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ilumetri

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label of the pre-filled syringe after EXP. The expiry date refers to the last day of that month.

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 a pre-filled syringe from the refrigerator, wait approximately 30 minutes to allow the Ilumetri 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 taken out of the refrigerator, do not store tildrakizumab above 25 °C or refrigerate it again. Write down the date of removal from the refrigerator in the space provided on the outer carton and appropriate discard date. 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 any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ilumetri contains

- The active substance is tildrakizumab. Each pre-filled syringe contains 100 mg of tildrakizumab.
- The other ingredients are L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose and water for injections.

What Ilumetri looks like and contents of the pack

Ilumetri is a clear to slightly opalescent and colourless to slightly yellow solution.

Ilumetri is available in unit packs containing 1 pre-filled syringe and in multipacks comprising 2 cartons, each containing 1 pre-filled syringe.

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu/>.

INSTRUCTIONS FOR USE

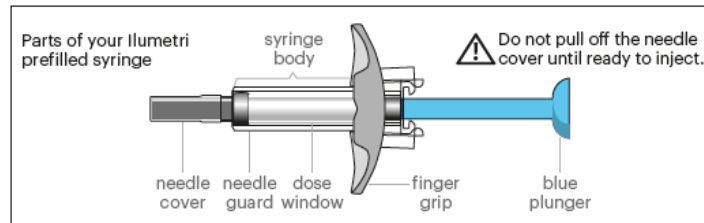
Before using the pre-filled syringes:

Important points to know

- Before you use Ilumetri 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.
- Read the Ilumetri Package Leaflet to learn more about your medicine.

PRODUCT DESCRIPTION

This is what Ilumetri pre-filled syringe looks like:



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.

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

- Leave the pre-filled syringe in the Ilumetri 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 Ilumetri visually for particulate matter and discoloration prior to administration.
 - Ilumetri 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.**



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.
 - **Choose a different location for the second injection.**

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.

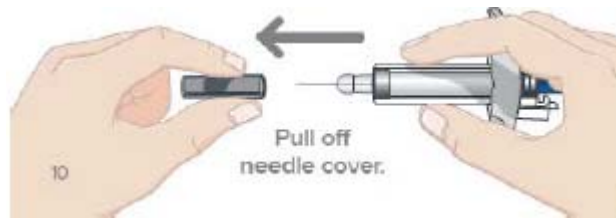


INJECTION

In case your dose is 200 mg, you will need to use 2 pre-filled syringes each time you administer the product.

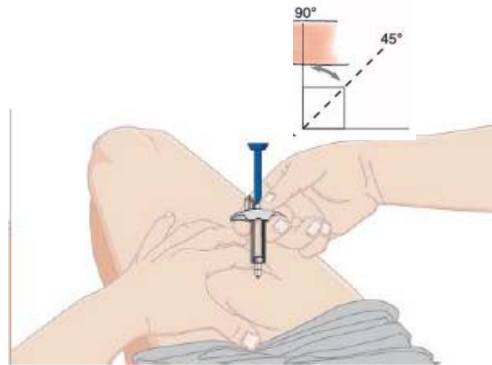
8. Pull off the needle cover

- 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, **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.



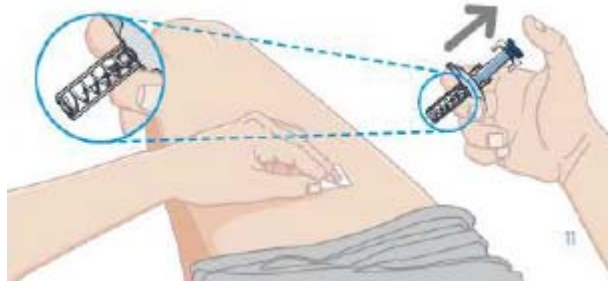
10. Inject

- 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 used syringe in a sharps disposal container right away after use and before injecting a second syringe.
- 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.
- Repeat the procedure with the second syringe in a different location of your skin if you are administering a dose of 200 mg.