APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ILUMYA® 100 mg/mL

(Solution for injection in pre-filled syringe)

tildrakizumab

Contains 70 mg sucrose per 1 mL single-dose prefilled syringe.

Read all of this leaflet carefully before you start using ILUMYA®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- ILUMYA® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ILUMYA® is and what it is used for

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.

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

2. What you need to know before you use ILUMYA®

Do not use ILUMYA®

- If you are allergic to tildrakizumab or any of the other ingredients of ILUMYA® (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

Tell your doctor or healthcare provider before being given the injection:

- 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.
- 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 or healthcare provider before using ILUMYA®.

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 using 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. Possible side effects).

Children and adolescents

ILUMYA® 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 ILUMYA®

Always tell your doctor or healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) These include vaccines and immunosuppressants (medicines that affect the immune system) as well. You should not be given certain types of vaccines (live vaccines) while using ILUMYA®**.** No data are available with the concomitant use of ILUMYA® and live vaccines.

Pregnancy, breastfeeding and fertility

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

It is preferable to avoid the use of ILUMYA® 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 ILUMYA® and for at least 17 weeks after treatment.

Driving and using machines

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

Sucrose

ILUMYA® contains 70 mg sucrose per dose. This should be taken into account if you have been diagnosed with diabetes mellitus.

3. How to use ILUMYA®

Do not share medicines prescribed for you with any other person.
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.

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

The recommended dose of ILUMYA® 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 ≥ 90 kg) 200 mg may provide greater efficacy.

Your doctor will decide for how long your treatment with ILUMYA® will last. If you have the

impression that the effect of ILUMYA® is too strong or too weak, tell your doctor or pharmacist.

After proper training in 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.

Use in children and adolescents

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

If you use more ILUMYA® than you should

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.

If you forget to use ILUMYA®

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

If you stop using ILUMYA®

The decision to stop using ILUMYA® 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, nurse or healthcare provider.

4. Possible side effects

ILUMYA® can have side effects. Not all side effects reported for ILUMYA® are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using ILUMYA®, please consult your doctor immediately.

Serious side effects

If you notice any of the following, stop using ILUMYA® and contact your doctor immediately or go to the casualty department at your nearest hospital:

- 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 (may affect more than 1 in 10 people)

- Upper respiratory infections

Common (may affect up to 1 in 10 people)

- Gastroenteritis
- Nausea
- Diarrhoea
- Injection site pain

- Back pain
- Headache

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ILUMYA®.

Suspected adverse reactions can also be reported directly to the Holder of Certificate for Registration (HCR) via email: pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

5. How to store ILUMYA®

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. 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 ILUMYA® solution in the syringe to reach room temperature (up to 25º 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 ILUMYA® above 25 º 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 dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

These measures will help to protect the environment.

6. Contents of the pack and other information

What ILUMYA® 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 ILUMYA® looks like and contents of the pack

ILUMYA® is a clear to slightly opalescent and colourless to slightly yellow solution.

ILUMYA® is available in unit packs containing 1 pre-filled syringe and packs comprising 2 pre-filled syringes.

Not all pack sizes may be marketed.

Holder of Certificate for Registration

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Registration number

59/30.5/0391

INSTRUCTIONS FOR USE

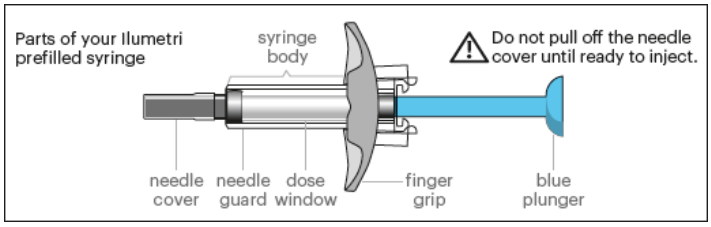
Before using the pre-filled syringes:

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.
- Read the ILUMYA® Package Leaflet to learn more about your medicine.

PRODUCT DESCRIPTION

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



PREPARATION

1. **Take a pack from the refrigerator** (if stored in the refrigerator)
   - Make sure the syringe dose corresponds to that prescribed by your doctor.
   - One syringe is needed for a 100 mg dose and two syringes are needed for a 200 mg dose.
   - 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 outer 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 expiry 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 if it contains visible particles or if 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.

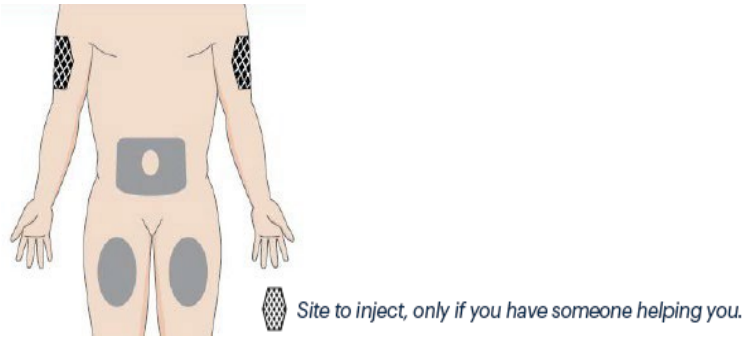
- ***DO NOT*** inject into scars, stretch marks, or blood vessels.
- The upper arm is only suitable when someone else is injecting you.
- Choose a different location for the second injection.

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.

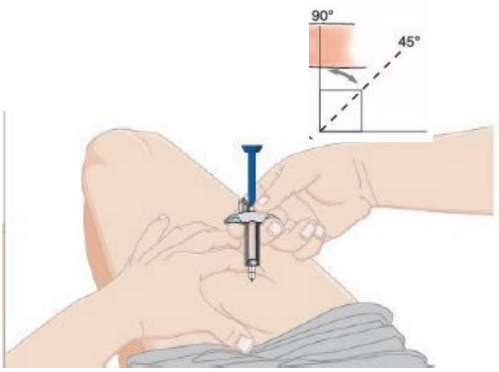


8. Pull off the needle cover

- 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.

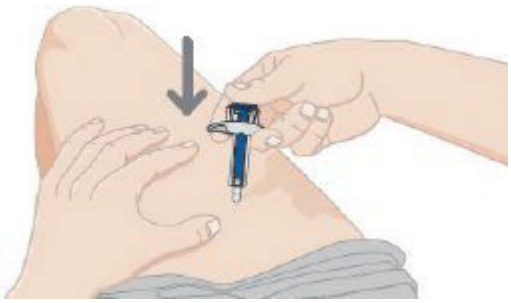
9. Pinch skin and insert needle

- 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.



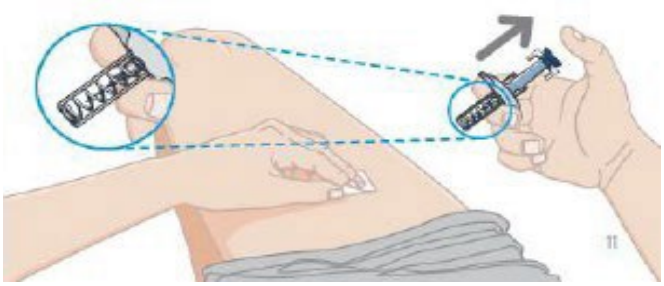
10. Inject

- 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 safely 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.