



**Almirall**

**Illumetri**

**Storyboard/Script**

6/30/22 | Version 6b

Illumetri is a prescription drug that can only be provided under medical advice. It is used to treat plaque psoriasis in adults with moderate to severe disease.

Illumetri 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.

*Initial screen with safety information. Will use the verbiage found in storyboard.*

**VO: Read the instructions for use before injection administration. After training you will be able to inject it at home, but talk with your doctor if you have any questions or concerns.**



*Open with scene of woman 2 (around 40 years old) preparing a suitcase for a business trip.*

VO: You've been prescribed Ilumetri, it is used to treat a skin condition called plaque psoriasis, in adults with moderate to severe disease. Using will benefit you by improvements of skin clearance and reducing your symptoms.



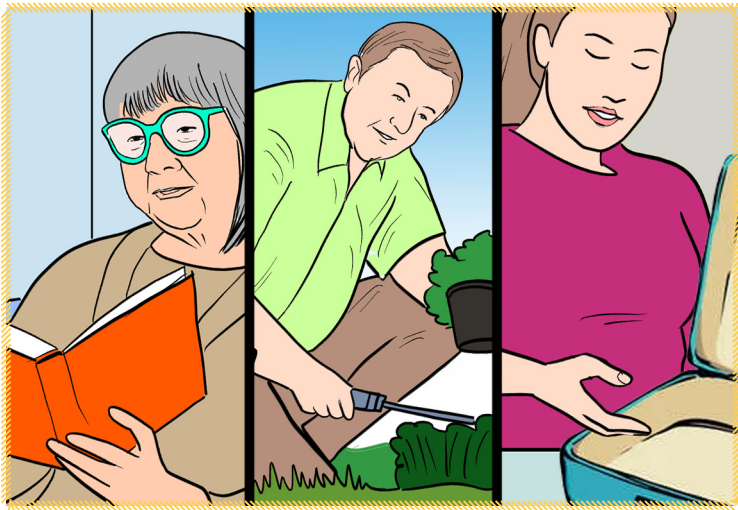
*Cut to man (heavy-set man around 50 years old) working in home garden.*

VO: Your doctor should explain to you how to use the pre-filled pen and you should read the full Instructions for Use contained in the carton.



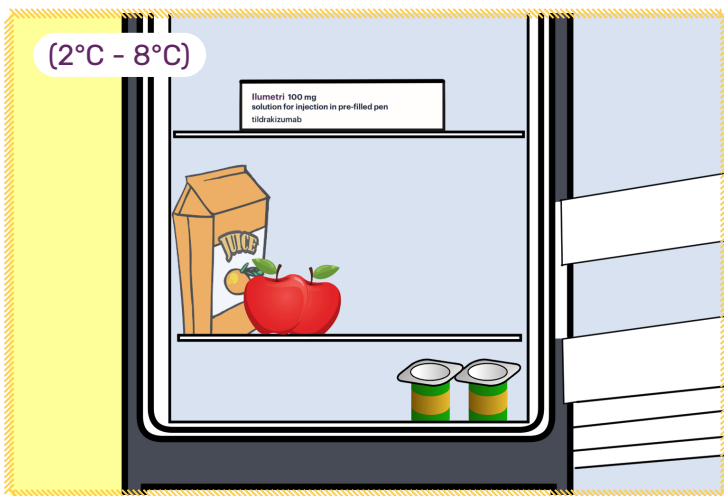
*Cut to woman 1 (elderly woman around 70) reading a book.*





*All three patients are shown on the screen doing a daily activity.*

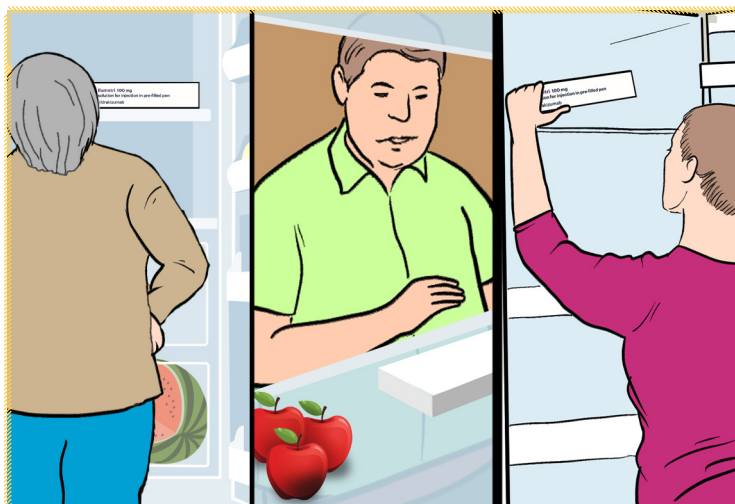
VO: Let's see how the ILUMETRI pre-filled pen can be administered while you go about your day.



*Shot of carton in upper shelf of refrigerator.*

VO: First, make sure you keep the medicine out of reach of children. Store the carton in the refrigerator. It should never be frozen.

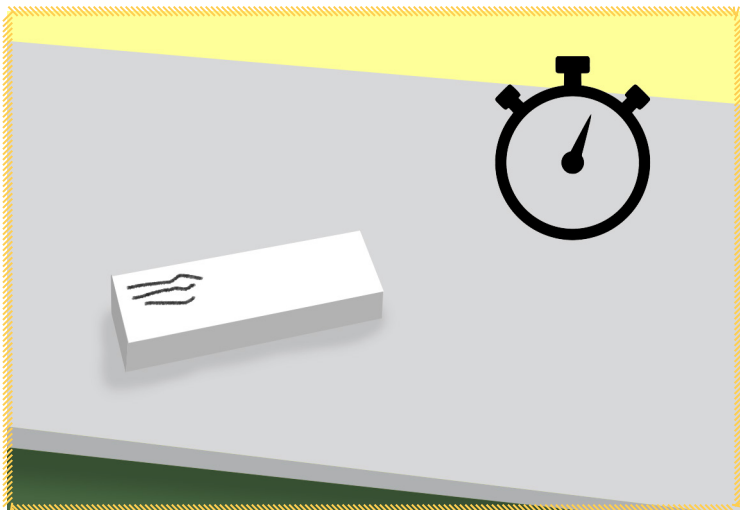
The product must be protected from light so keep it in the original carton until the time of use. Do not shake and keep it on a flat surface.



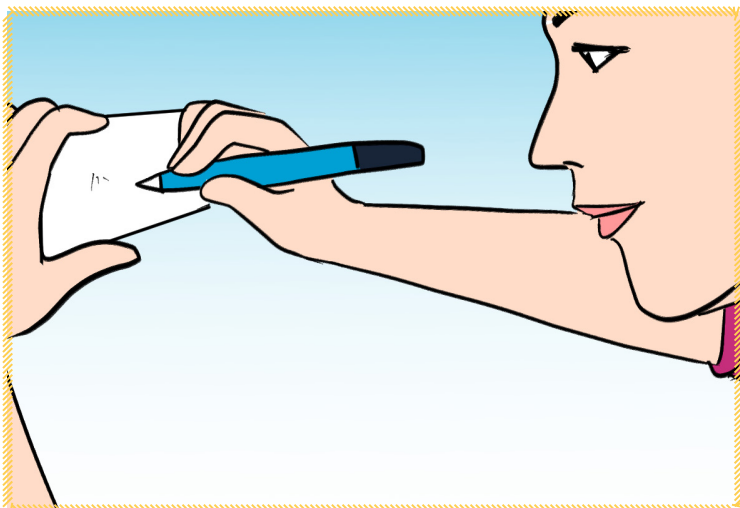
*Shot of all three patients removing the medication from their refrigerators.*

VO: When it's time to administer your medication, take the carton out of the refrigerator and allow the carton with the pre-filled pen to come to room temperature. This is typically around thirty minutes.



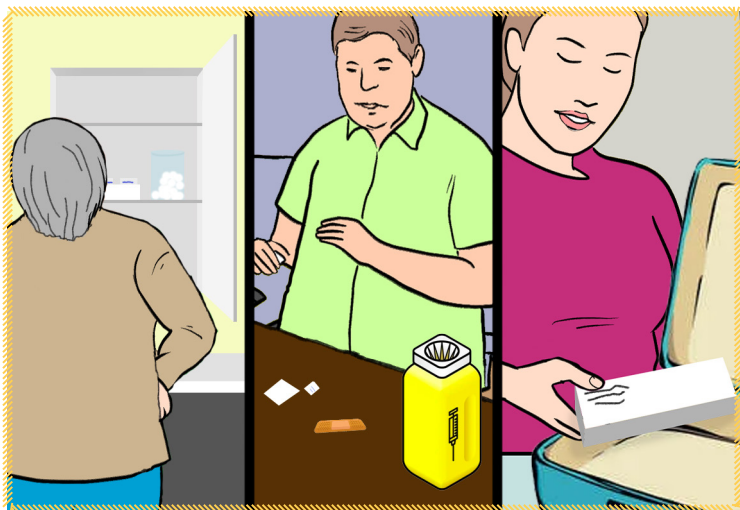


*Shot of medication on table with elapsed timer showing thirty minutes.*



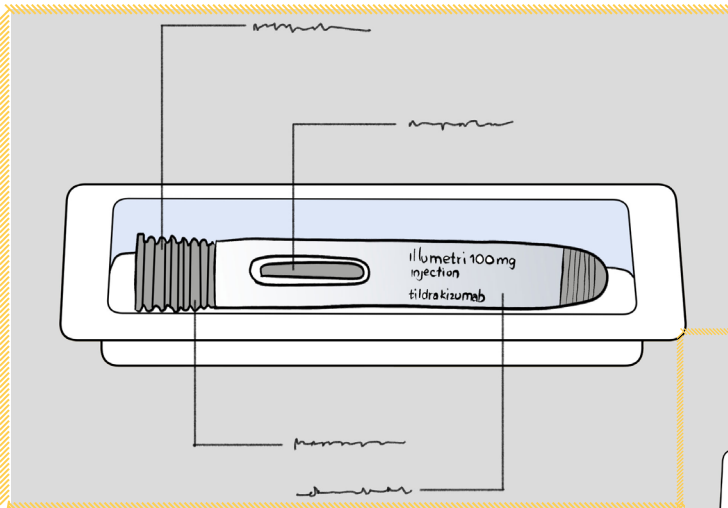
*Close-up of woman 2 writing on carton date.*

VO: If you are not going to use the medication immediately, make sure you mark on the carton when you removed the medicine from the refrigerator in the space provided. The medicine can only be out of the refrigerator for a maximum of thirty days and once it is removed from the refrigerator it cannot be put back in.



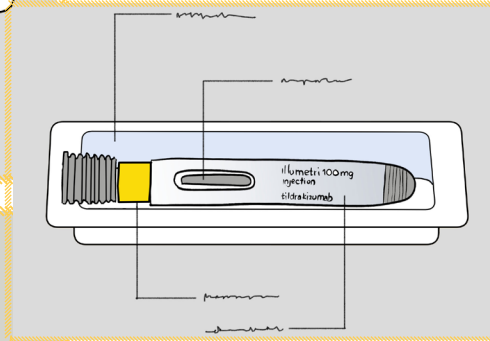
*All three patients gathering supplies. Woman two is packing medication for travel.*

VO: While you wait for the medicine to come to room temperature, gather the additional supplies you will need. This includes an alcohol swab, cotton ball or gauze pad, adhesive bandage as well as a sharps disposal container.



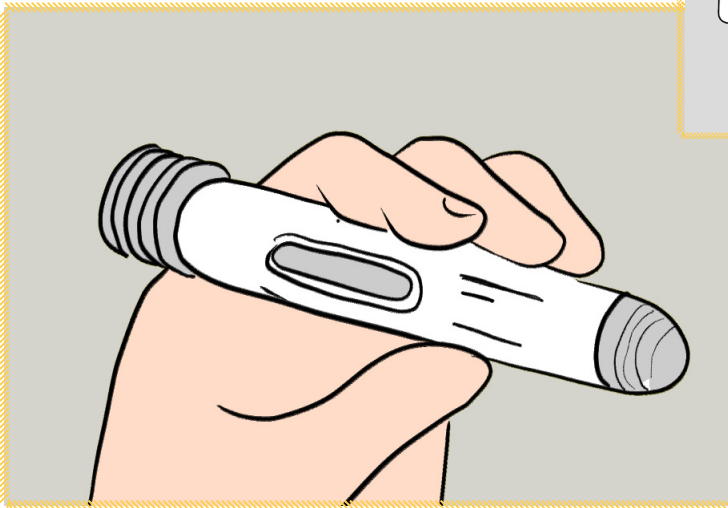
*Overhead view of pre-filled pen on a tray, cap will slide to left to show needle guard then move back.*

VO: Now let's look at the components of the Illumetri pre-filled pen. You have the Gray needle cap, the yellow needle guard under the needle cap, remember to not remove the grey needle cap yet. The viewing window and the label information that contains the expiration date and dose information.



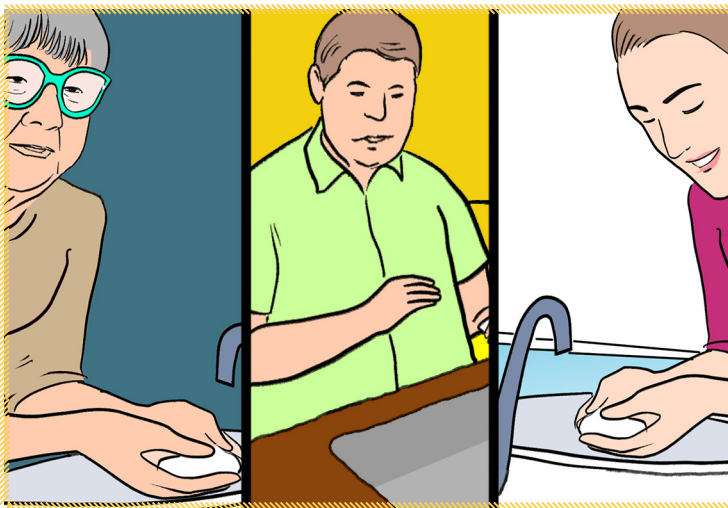
*Close-up view of pen with the expiration date and viewing window prominent.*

VO: Check the label information to make sure the expiration date has not passed. Also check the viewing window to make sure the liquid is clear or have a slight yellow hue and there is not any particles or discoloration. There maybe one or more air bubbles which is normal.

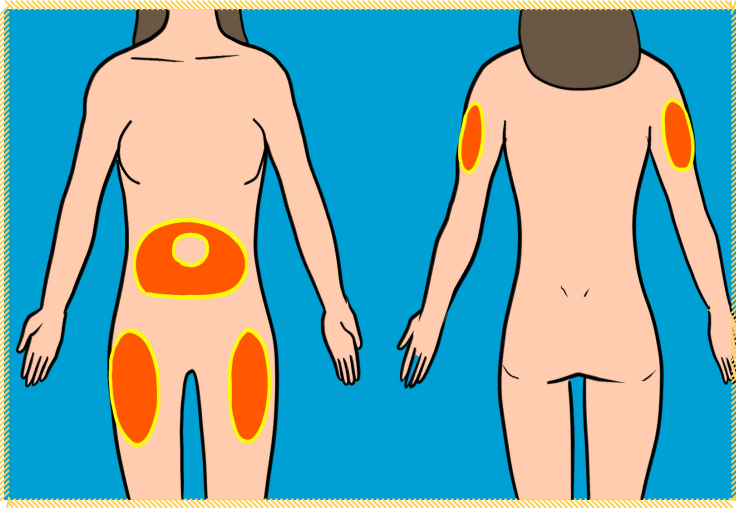


*All three patients washing their hands thoroughly.*

VO: Wash your hands well with soap and water, then dry your hands.



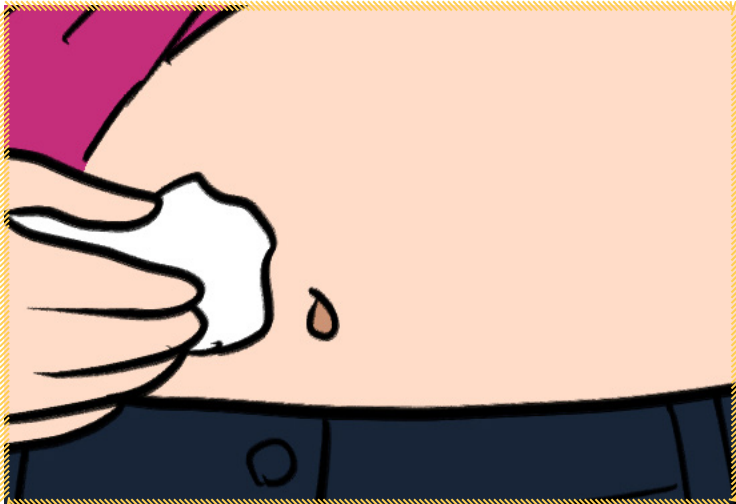




*Graphic overlay of the available injection sites.*

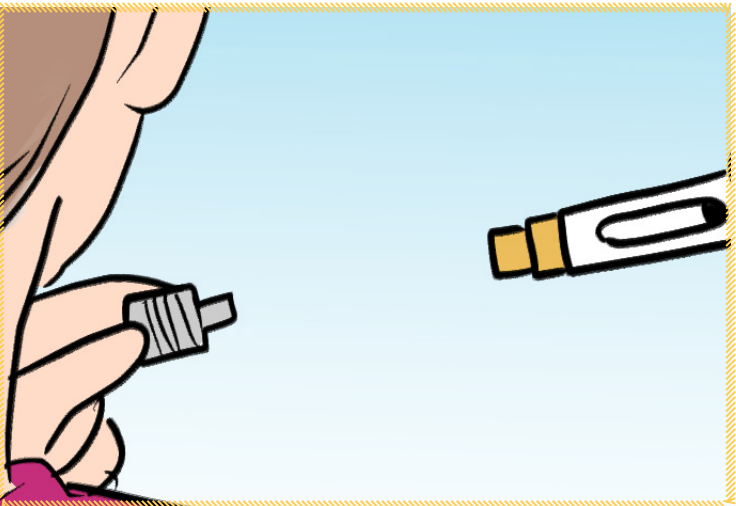
VO: Next, choose an injection site. This can be the front of the thighs, abdomen, except for two inches around belly button, or the back of the upper arms. Do not inject into skin that is tender, red, bruised or affected by psoriasis. Also, do not inject into scars or blood vessels.

If injecting in the upper arm, make sure you have easy access or use the help of another individual.



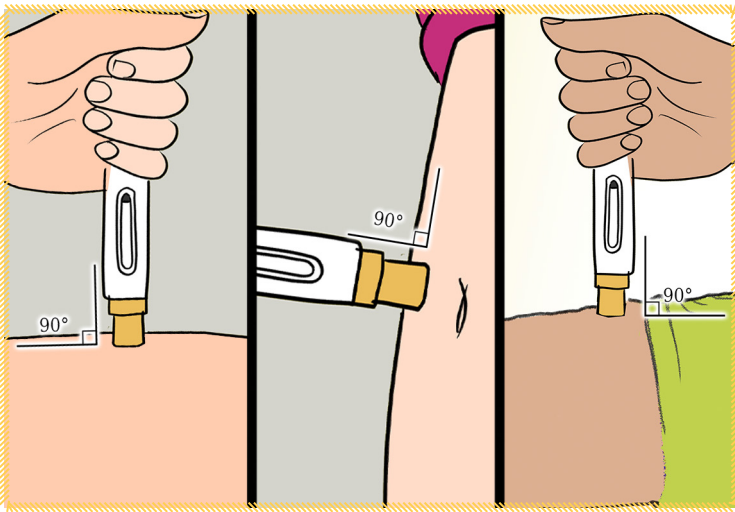
*Medium shot of woman 2 cleaning her abdomen with alcohol swab.*

VO: Now clean the chosen injection site with an alcohol swab allowing it to air dry. Do not blow or touch the site after it has been cleaned.



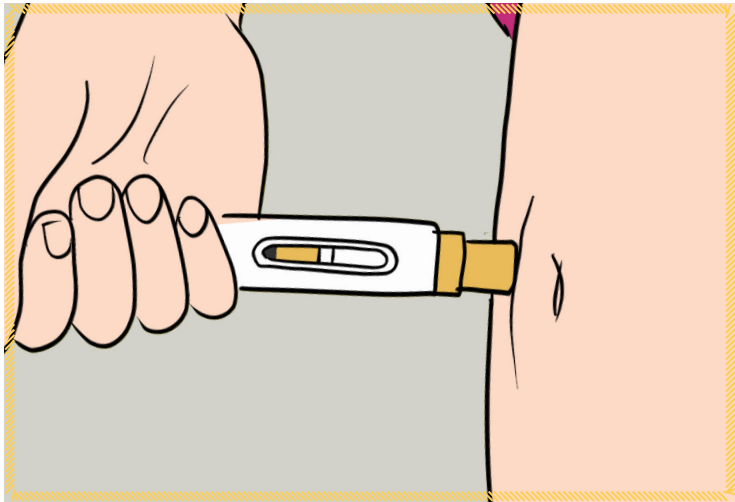
*Medium shot over shoulder of woman 2 removing the cap from the pre-filled pen.*

VO: Then, remove the gray needle cap from the pre-filled pen by pulling it straight off. It may require some force to remove. This will reveal the yellow needle guard. Never touch the yellow needle guard with your hands.



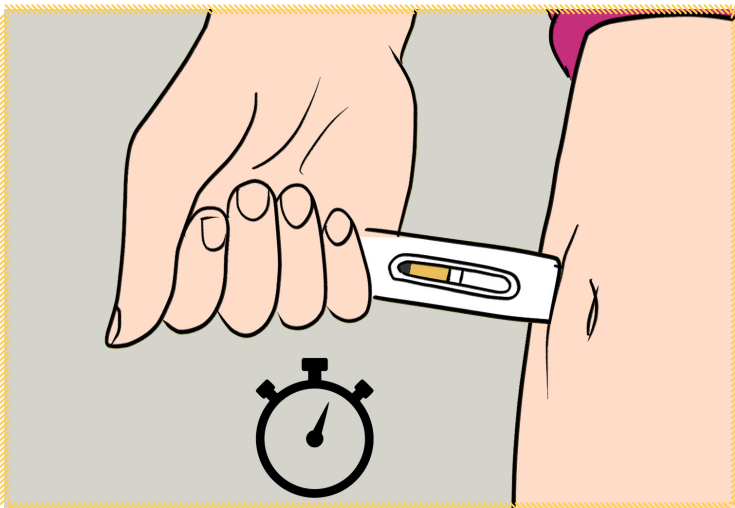
*Close up shot of pre-filled pen being placed on the abdomen for woman 2 and thigh for woman 1 & man 1. (We will film both pinching the skin and not pinching the skin to align with the PIL once finalized)*

VO: Place the pre-filled pen straight on the cleaned injection site at a 90-degree angle. Make sure you can see the viewing window.

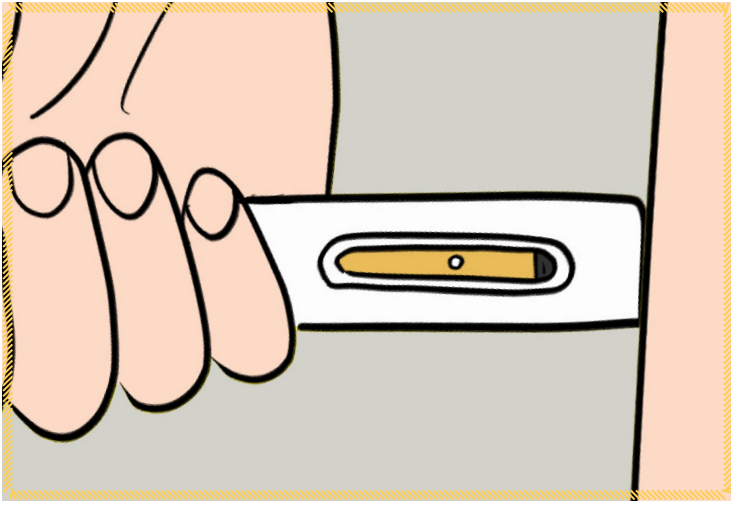


*Close up shot of pre-filled pen on skin pushed down so no needle guard is shown.*

VO: To start the injection, press and hold the pre-filled pen all the way down against the skin. You will see the yellow needle guard slide up into the pen. You will hear the 1st click that lets you know the injection has begun.

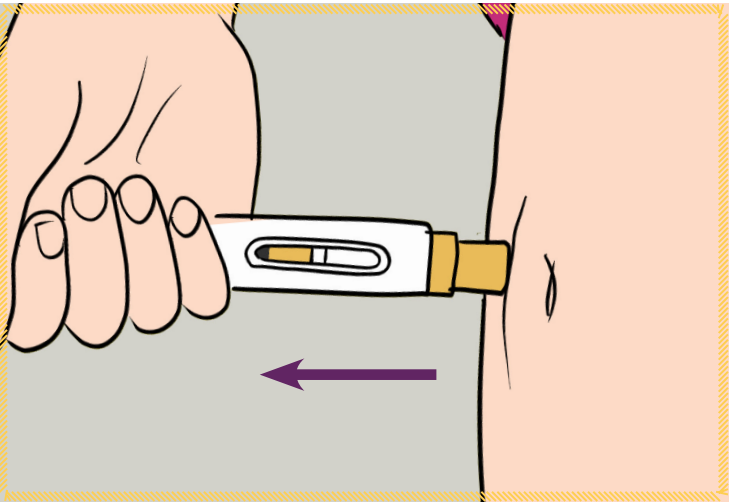


VO: Count slowly to 15 seconds, during this time you will hear a second click letting you know the injection is almost done. Make sure you wait the full fifteen seconds and hear the second click.

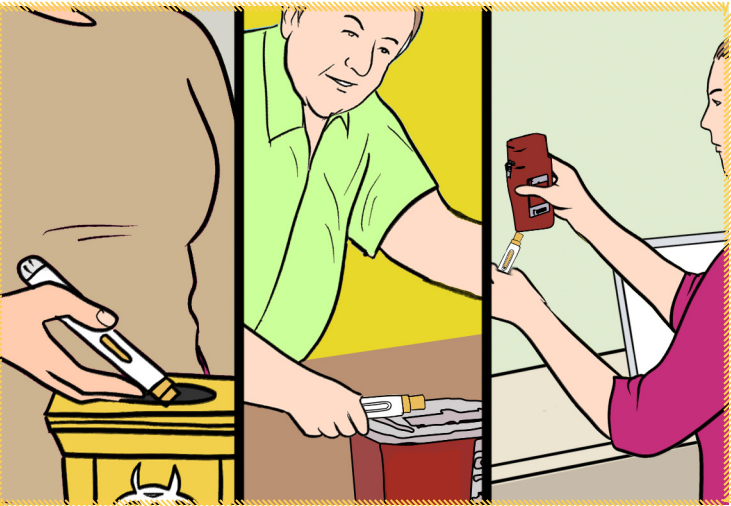


*Close up shot of the inspection window that is completely yellow.*

VO: Now look at the inspection window, it should completely be filled with yellow. You can now lift the pre-filled pen straight up.



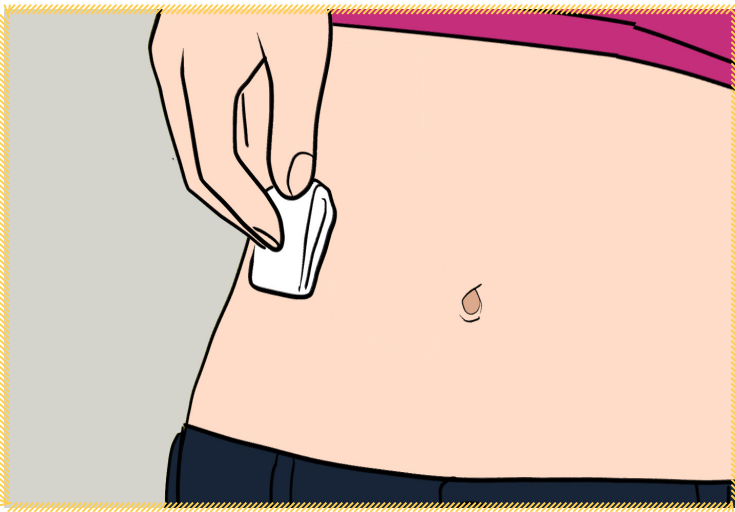
*Wide shot of lifting the pre-filled pen straight up.*



*All three patients placing pre-filled pen in sharps containers.*

VO: Immediately discard the pre-filled pen in a sharps disposal container. If you do not have a sharps container, follow your local guidelines for disposal.



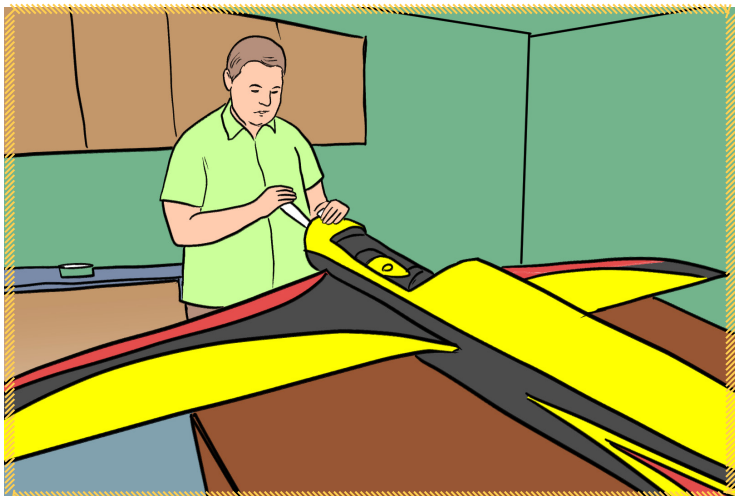


*Close up shot of injection site with woman 2 about to put cotton ball on slight bleeding.*

VO: If any bleeding occurs, use the cotton ball or gauze pad on the area. Apply and adhesive bandage as needed. You may feel a slight sensation following the injection. Contact your physician if any local reaction is experienced.



*Woman 1 walking around house.*



*Man putting together a model airplane on a table.*

VO: This completes the administration of the Ilumetri pre-filled pen.





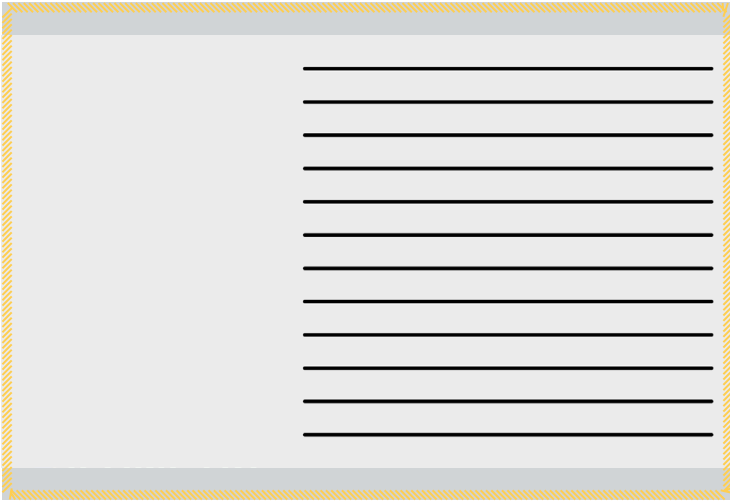
*Woman 2 in conference room working.*



**Website & Info Screen**

VO: If you have any questions or need more information, talk to your doctor.

VO: Please keep watching to see important safety information about Ilumetri.



## Package leaflet information

### *(Text Only - Placeholder until final version is ready, not formatted)*

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.

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- 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 section 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.

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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 (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 side effects

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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 national reporting system listed in Appendix V. 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. 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 packs comprising 2 pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

SUN Pharmaceuticals Industries (Europe) B.V.

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This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu/>.