

## **ILUMETRI® PATIENT TREATMENT BOOKLET**

You have been prescribed ILUMETRI® to treat psoriasis.  
This brochure contains all the important information you need to know about your  
treatment with ILUMETRI®.

## WELCOME

### DEAR PATIENT,

You and your doctor have decided to treat your psoriasis with ILUMETRI®.

When psoriasis reaches a certain severity level, treatment with systemic medication (that works throughout the body) is recommended.

The most important contact person for all questions relating to your condition and treatment with ILUMETRI® is your dermatologist. We would like to provide this brochure as a supplement with information on psoriasis and treatment with ILUMETRI®.

More information about the symptoms of psoriasis can be found at [www.almirall.de](http://www.almirall.de) in the "Patients with psoriasis. Tips and information" guide.

We wish you every success with your treatment!

Your Almirall team

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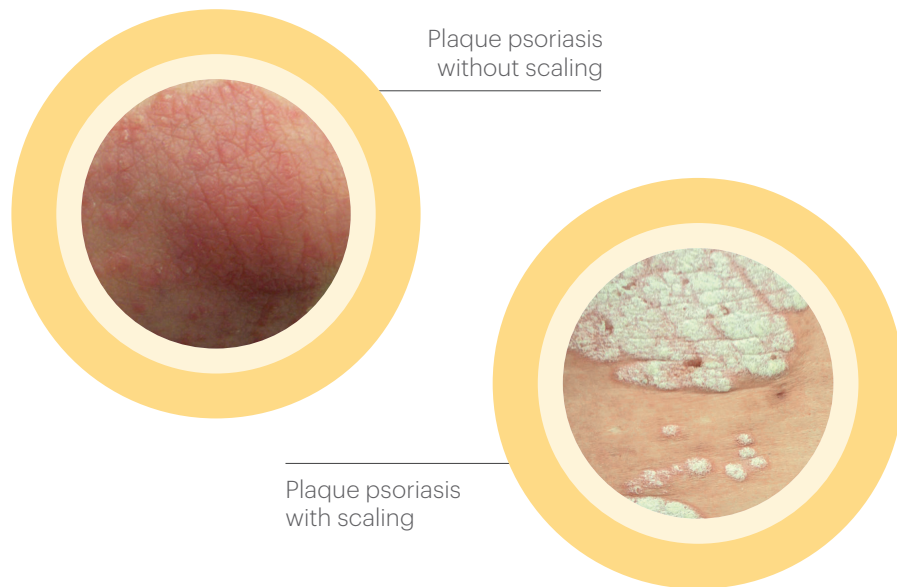
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**WHAT IS PSORIASIS?**

Psoriasis is a chronic inflammatory condition that affects around 2 per cent of the population (approx. 1.5 million people) in Germany.

The most common form of psoriasis is Psoriasis vulgaris (plaque psoriasis). It appears as red, clearly defined areas of skin that are covered with a silvery-white build-up of dead skin cells (plaques). The appearance of psoriasis can vary considerably from patient to patient.

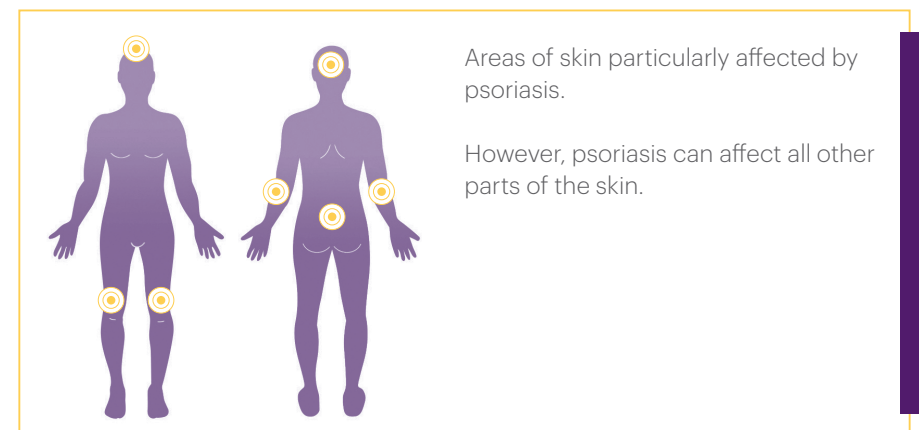


Psoriasis is very frequently accompanied with itching. The skin on the psoriasis plaques, which is usually very dry and loses its elasticity, can form superficial and painful cracks on areas of the body that are subjected to more stress (for example on the extensor surfaces of the joints).

**WHAT AREAS OF THE BODY ARE AFFECTED – WHAT ARE THE SYMPTOMS?**

Psoriasis can occur in various severity levels and on different parts of the body – from minimal, barely visible skin changes to severe, large areas of skin changes on single or several parts of the body.

The areas frequently affected by psoriasis are the elbows and knees, the lower back around the spine and the scalp.



Areas of skin particularly affected by psoriasis.

However, psoriasis can affect all other parts of the skin.

## CAUSE

### WHAT CAUSES PSORIASIS?

Patients with psoriasis suffer from an immune overreaction of the body for reasons that are not yet scientifically known.

Certain parts of the immune system are so active that they trigger persistent inflammation. Many different immune cells are involved in this inflammation, some of which migrate to the skin after they are activated, where they release different proinflammatory mediators.

It is not yet known why the immune system triggers this kind of inflammatory reaction. However, some of the factors involved in this inflammatory process are known today: As far as is known, interleukin-23 (IL-23) is considered the central regulating mediator that controls the activation of certain immune cells.

These activated immune cells produce various inflammatory factors and transmit them to the surrounding tissue. This causes the inflammation that results in psoriasis.

## TREATMENT

### HOW IS PSORIASIS TREATED?

The treatment selected is based on the degree of severity of the condition. Mild forms of psoriasis are usually treated with topical medications such as creams or ointments.

Moderate to severe psoriasis is usually treated with systemic medication, such as tablets or injections and/or UV light therapy. Some patients are given a combination of treatments.

Regardless of the treatment selected, it is usually accompanied by a concomitant basic treatment with soothing creams and ointments.

**WHAT IS ILUMETRI®?**

**ILUMETRI® 100 mg injection solution in a pre-filled syringe** is a medication that has been approved to treat adults with moderate to severe plaque psoriasis.

ILUMETRI® contains the active ingredient tildrakizumab and is available as a pre-filled syringe. ILUMETRI® is administered by means of injection under the skin (subcutaneous).

Tildrakizumab belongs to a group of medications that are referred to as interleukin (IL) inhibitors. Tildrakizumab selectively inhibit interleukin 23 (IL-23) and is a so-called biologic.

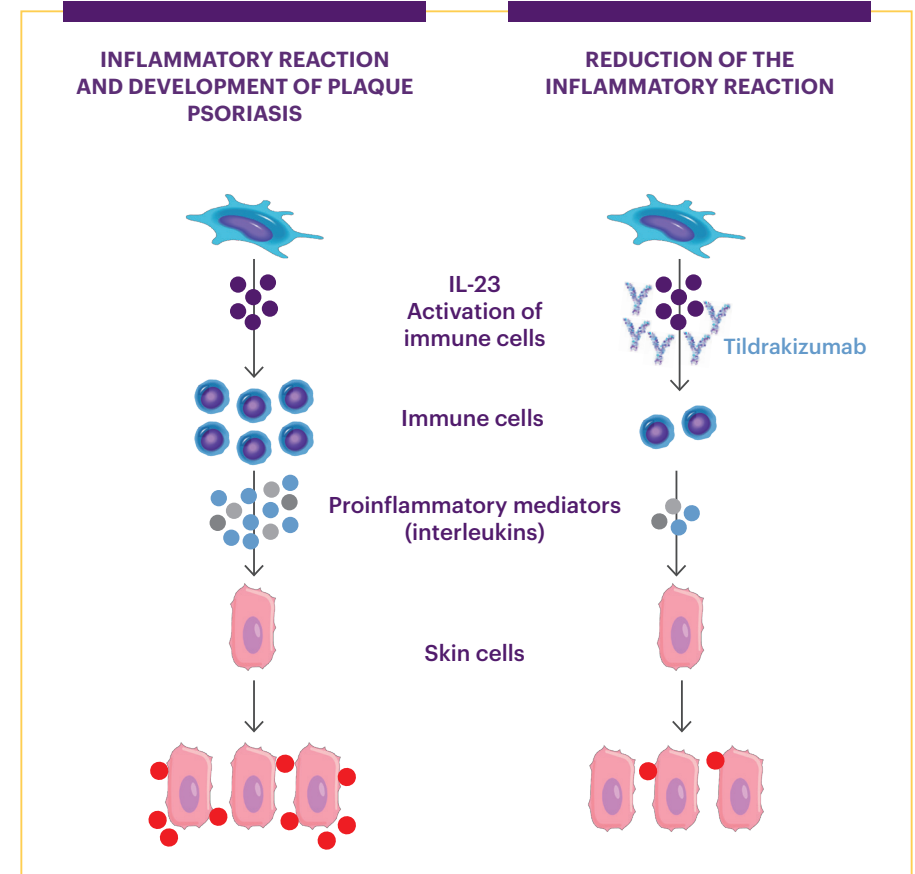
Biologics are medications manufactured from biological sources that are very similar to the body's own substances and target overreactions of the body's own defences.



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**HOW DOES ILUMETRI® WORK?**

ILUMETRI® contains the active substance tildrakizumab, which inhibits interleukin-(IL). Interleukins are the body's mediators that control communication between the immune cells. Tildrakizumab inhibits the activity of interleukin-23 (IL-23), the central regulating mediator of the inflammatory reaction in psoriasis. This inhibition results in an improvement in the skin and a reduction in the symptoms of psoriasis after using tildrakizumab or ILUMETRI®.





## QUICK INSTRUCTIONS

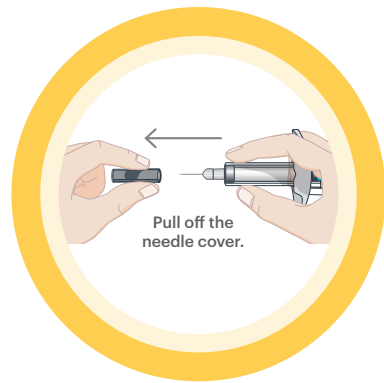
If your doctor has prescribed a dose of  $2 \times 100$  mg ILUMETRI®, **select a different site for the second injection.**

### Clean the injection site

- Clean the injection site with an alcohol swab and let your skin dry. Do not touch the site again before the injection.

## 3. INJECTION

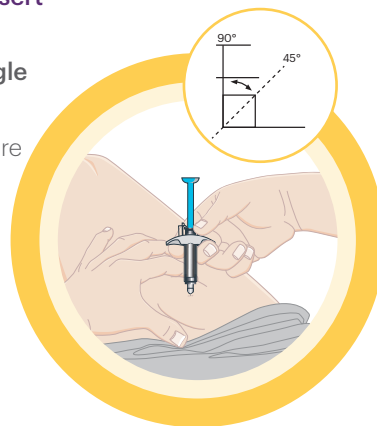
### 3.1. Pull off the needle cover



- Hold the pre-filled syringe by the barrel, pull off the needle cover as shown and dispose of it. One or two drops of liquid may drip out; this is normal.
- Do NOT touch the blue plunger yet.
- Do NOT use if the pre-filled syringe or needle is bent.

### 3.2. Gently pinch the skin at the injection site and insert the needle

- Completely inject the needle **vertically at a 90° angle** into the skin pinched between your fingers.
  - Do NOT put your finger on the plunger while you are inserting the needle.
- Hold the syringe steady.

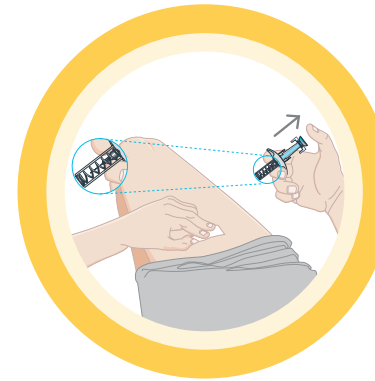
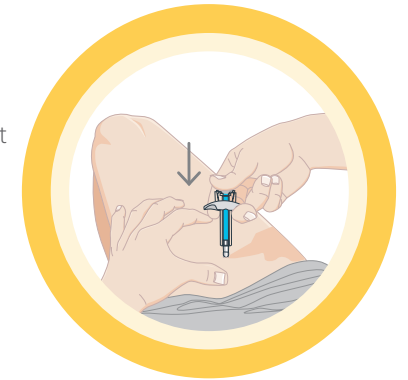


## QUICK INSTRUCTIONS

### 3.3. Inject the medication

- Once you have injected the needle, carefully let the skin go.
- Now push down on the blue plunger to inject all of the solution.

A full dose has been administered once the blue plunger has been pushed down fully and no liquid leaks out.



- Completely remove the needle from the skin before you release the blue plunger. Once you release the blue plunger, the safety mechanism retracts the needle into the needle guard.

## 4. DISPOSE OF THE USED SYRINGE

Dispose of the used syringe immediately after use.

**More information on ILUMETRI® and the extended version of the instructions can be found in the ILUMETRI® package insert.**

## WHAT YOU NEED TO KNOW BEFORE USE

### WHAT YOU NEED TO KNOW BEFORE USE

The most important contact person for all questions relating to treatment with ILUMETRI® is your dermatologist. Before treatment begins, your doctor will examine you for possible tuberculosis infections.

Please inform your doctor before you begin treatment if you have any known allergies, acute and chronic infections (e.g. tuberculosis, hepatitis), current and scheduled vaccinations and medication that you are taking.

Please also read the ILUMETRI® package information (package insert).



#### BEFORE TREATMENT, INFORM YOUR DOCTOR ABOUT:

- known allergies
- acute and chronic infections (e.g. tuberculosis, hepatitis)
- current and scheduled vaccinations
- medication you are taking



## UNDESIRABLE EFFECTS



#### CHECK FOR INFECTIONS AND ALLERGIC REACTIONS:

ILUMETRI® may cause severe undesirable effects, including infections and allergic reactions. If you notice signs of a possible severe infection or an allergic reaction, do not administer any more injections and contact your doctor immediately or seek medical advice.

Please also read the package information (package insert).

#### SUSPECTED UNDESIRABLE EFFECTS

During treatment with ILUMETRI®, undesirable effects may occur as with any other medication.

If you experience any undesirable effects, inform your doctor.

The most common undesirable effects include infections in the upper respiratory tract, gastroenteritis, nausea, diarrhoea, pain at the injection site, back pain and headaches (please see ILUMETRI® package insert).



## PREGNANCY

### PREGNANCY AND LACTATION

Use of ILUMETRI® during pregnancy should be avoided. If you are a woman of childbearing potential, you are advised to use an effective method of contraception during treatment and at least 17 weeks after the last dose of ILUMETRI®.

It is unknown whether tildrakizumab is excreted in human milk. If you are breastfeeding, the benefit of breastfeeding for the child as well as the benefit of treatment for the mother is to be taken into account. In humans, during the first few days after birth antibodies may be transferred to the newborn through milk. In this short period, a risk to the newborn/child cannot be excluded.

If you are breastfeeding, please inform your doctor and pharmacist and ask for advice.



## OTHER MEDICINES

### OTHER MEDICINES IN COMBINATION WITH ILUMETRI®

Tell your doctor or pharmacist if you are taking, have recently taken or might take other medicines. This also includes vaccines and immunosuppressants (medication that reduces the strength of the immune system).

## VACCINES

### ILUMETRI® AND VACCINATIONS

Certain types of vaccines (live vaccines) must not be administered during treatment with ILUMETRI®. Your doctor will discuss with you whether vaccines should be renewed according to the current vaccination guidelines before beginning treatment with ILUMETRI®.



## ABILITY TO DRIVE



### EFFECT ON ABILITY TO DRIVE

ILUMETRI® has no or negligible influence on the ability to drive.

## TREATMENT SUCCESS

### HOW CAN YOU CONTRIBUTE TO THE SUCCESS OF THE TREATMENT?

Take this medication exactly in accordance with your doctor's instructions. If you self-administer the subcutaneous injections, do not discontinue using ILUMETRI® without prior consultation with your doctor.

Discontinuing treatment may cause your symptoms to reappear. Please read the package information carefully before beginning treatment and contact your doctor or pharmacist if anything is unclear or you have any further questions about the treatment.

## SELF-HELP ORGANISATIONS

### SELF-HELP GROUPS/ORGANISATIONS

Many patients find speaking to other people who suffer from psoriasis to be very helpful and can make living with the condition easier. Self-help organisations and groups offer a platform where you can talk openly and in confidence about the condition and your experiences, as well as give each other information and tips. Below are the addresses and contact information of self-help organisations with local self-help groups in Germany, Austria and Switzerland:

#### GERMANY

Deutscher Psoriasis Bund e.V.  
(German Psoriasis Association)  
Seewartenstraße 10  
20459 Hamburg  
Telephone: +49 (0)40 22 33 99-0  
Fax: +49 (0)40 22 33 99-22  
Website: [www.psoriasis-bund.de](http://www.psoriasis-bund.de)  
E-mail: [info@psoriasis-bund.de](mailto:info@psoriasis-bund.de)

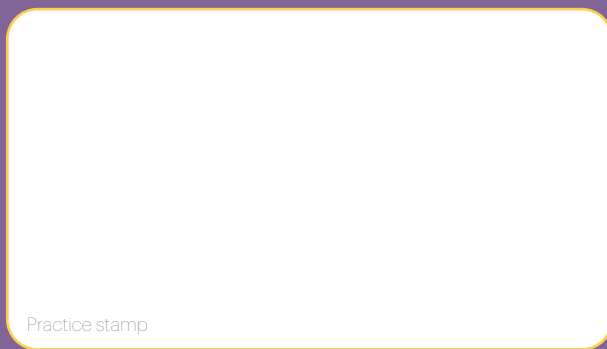
#### AUSTRIA

PSO-Austria Verein und Selbsthilfegruppe  
der PsoriatikerInnen in Österreich (PSO-  
Austria Association and Self-help Group  
in Austria)  
Obere Augartenstraße 26–28/1.18  
1020 Vienna  
Telephone: +43 (0)664 731 119 91  
Website: [www.psoriasis-hilfe.at](http://www.psoriasis-hilfe.at)

#### SWITZERLAND

SPVG Schweizerische Psoriasis- und Vitiligo-Gesellschaft  
(SPVG Swiss Psoriasis and Vitiligo Organisation)  
Scheibenstraße 20  
3014 Bern  
Telephone: +41 (0)31 359 90 99  
Website: [www.spvg.ch](http://www.spvg.ch)





You can find more information at: [www.almirall.de](http://www.almirall.de)

**1.** Summary of product characteristics for ILUMETRI<sup>®</sup>. Version: September 2018. **2.** Nast, A. et al., S3 guideline on the treatment of psoriasis vulgaris, Update 2011. JDDG: Journal of the German Dermatological Society, 2011. 9: p. S1–S104. **3.** Nast, A., European S3-guidelines on the systemic treatment of psoriasis vulgaris, Update 2015. <http://www.euroderm.org/edf/index.php/edf-guidelines>, 2015.

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