

Getting started with TREMFYA[®] (guselkumab)



Information for people being treated
with TREMFYA for plaque psoriasis



janssen  Immunology

PHARMACEUTICAL COMPANIES OF 



Your doctor has prescribed TREMFYA (guselkumab) as a treatment for your psoriasis. Psoriasis is a condition in which the immune system mistakenly attacks the body's skin, often causing painful inflammation.

WELCOME TO TREMFYA

TREMFYA belongs to a group of treatments called monoclonal antibodies. It is also sometimes called a biologic or a biological treatment, which is used to treat severe inflammatory conditions. This type of treatment can help with symptoms, and also address the inflammation and physical changes in your skin.

Your doctor has given you this booklet to help you understand your treatment with TREMFYA – why he or she has chosen TREMFYA for you and what you should expect from treatment. We hope it will answer some of the questions you have, but it does not replace the advice of your doctor and other healthcare professionals. If you have any questions or concerns, make sure you discuss them with your doctor or nurse. You might find it helpful to jot down any questions or concerns you would like to discuss on page 23 of this booklet and take it with you to your next appointment.

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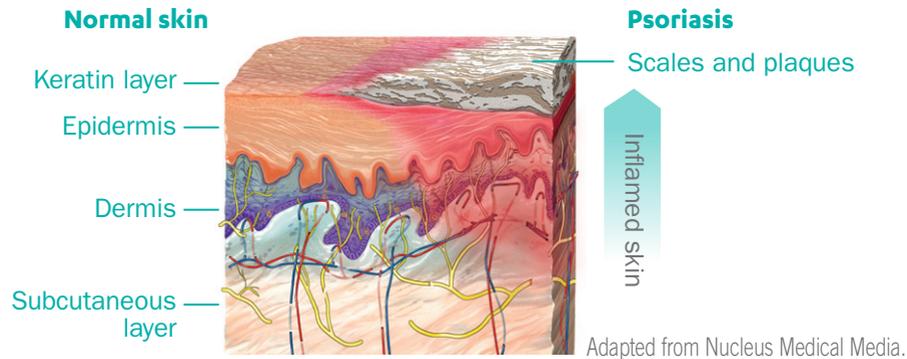
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BACKGROUND INFORMATION ON PSORIASIS

What is psoriasis?

Psoriasis is a multi-system disease which most commonly presents on the skin. The disease changes the life cycle of skin cells causing cells to build up rapidly on the surface of the skin. The extra skin cells form thick, silvery scales and itchy, dry, red patches (plaques) that are sometimes painful.



Psoriasis is not infectious or contagious – which means you do not ‘catch’ it, and you cannot pass it on to anyone else. It is a chronic condition. This means once it develops, it continues for life, even though it can get better or worse over time and may even seem to disappear for lengthy periods.

How common is it?

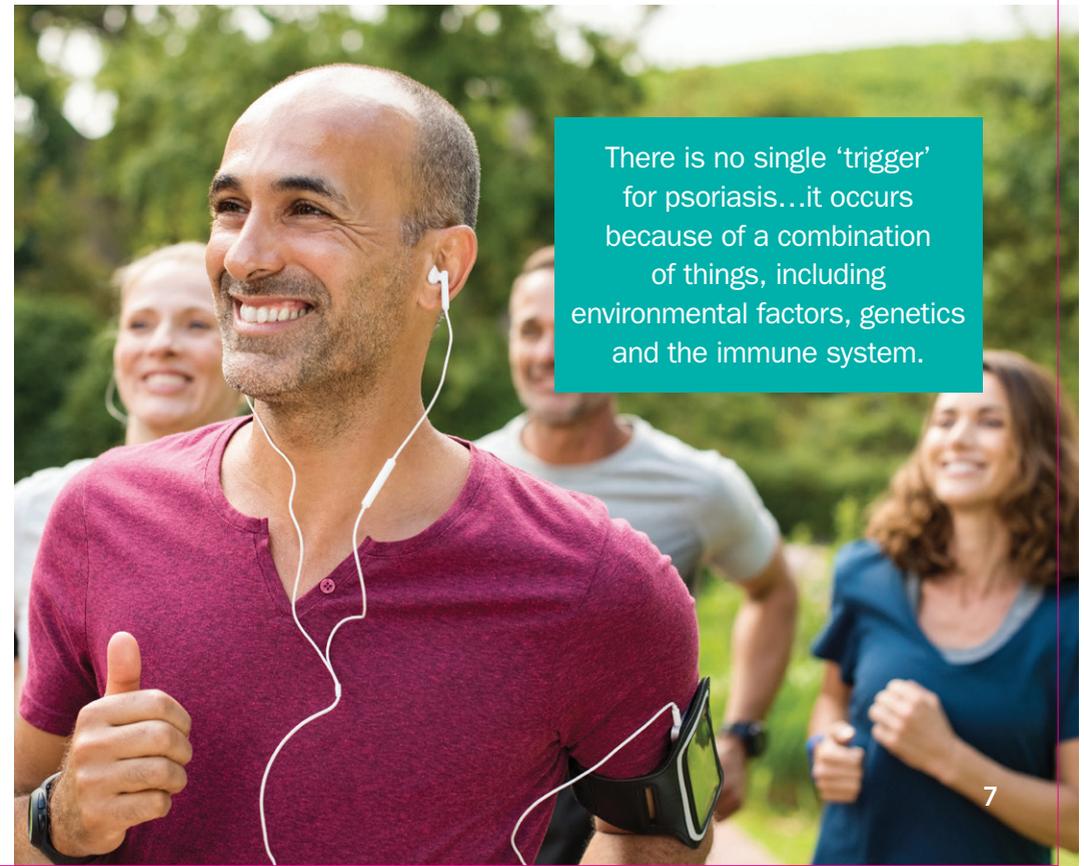
About 2.3–6.6% of Australians are living with psoriasis.¹ Both men and women can develop it, and although the disease occurs in all age groups, the condition usually starts in young adults in their early 30s, with 75% of affected people developing psoriasis before the age of 45 years.²



What causes it?

Psoriasis is an autoimmune condition, which means it is caused by an overactive immune system. This causes immune cells to constantly act as though they are fighting an infection or healing a wound. It leads to the abnormally rapid rate of skin cell multiplication, which results in skin cells that build up and cause the thickened scaly patches of psoriasis. The immune system is not compromised – it is simply working too fast.

There is no single ‘trigger’ for psoriasis. Instead, it occurs because of a combination of things, including environmental factors, genetics and the immune system. For example, whilst inherited factors are known to be important, not everyone with a family history develops psoriasis. This means that environmental triggers, such as stress, an infection, smoking or alcohol, may play a role in the initial development of the disease.



TREATING PSORIASIS

While there is no cure for psoriasis, symptoms can be decreased, and in some cases disappear, if they are well managed with treatment. A variety of treatments is available for psoriasis, and which is best for you will depend on a number of factors. In making a treatment decision, your dermatologist will consider with you: the severity of your condition, its location, how it is affecting your quality of life and whether you have other health concerns.

Finding the best treatment plan for you can take some time. When developing a treatment plan, your doctor will mostly follow a step-by-step approach. This approach works through the various therapies as necessary for your condition. By doing this, your doctor ensures that the best treatment for the severity of your condition is chosen for you, as your response to treatment may change over time.



ABOUT TREMFYA

TREMFYA contains the active substance guselkumab – a type of protein known as a monoclonal antibody. TREMFYA is used to treat adults with moderate-to-severe plaque psoriasis and works by neutralising the activity of another type of protein called interleukin 23 (IL-23). IL-23 has been shown to be present in people with psoriasis at increased levels. By neutralising the activity of IL-23, TREMFYA can help to reduce the symptoms of psoriasis, such as scaling, shedding, flaking, itching, pain and burning.

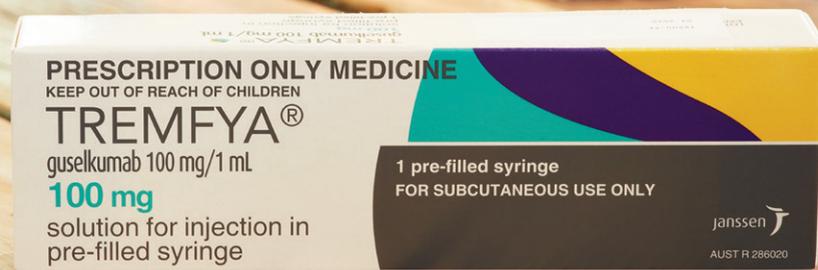
Before starting treatment with TREMFYA

Check with your doctor before starting treatment with TREMFYA, if you:

- are being treated for an infection
- have an infection that does not go away or keeps coming back
- have tuberculosis (TB) or have been in close contact with someone who has TB
- think you have an infection or have symptoms of an infection, such as:
 - fever or flu-like symptoms
 - blood in your phlegm (mucus)
 - muscle aches
 - cough
 - shortness of breath
 - weight loss
 - diarrhoea or stomach pain
 - burning when you urinate or urinating more often than normal
 - warm, red or painful skin, or sores on your body different from your psoriasis
- have recently had a vaccination or are due to have a vaccination
- are about to start taking a new medicine, tell your doctor and pharmacist that you are taking TREMFYA
- are planning a pregnancy or you become pregnant while using TREMFYA
- plan to breastfeed while using TREMFYA.

After starting TREMFYA, talk to your doctor straight away if you have any symptoms of an infection as listed above.

Symptoms of psoriasis can be decreased, and in some cases, disappear, if they are well managed with treatment.



Do not use TREMFYA if:

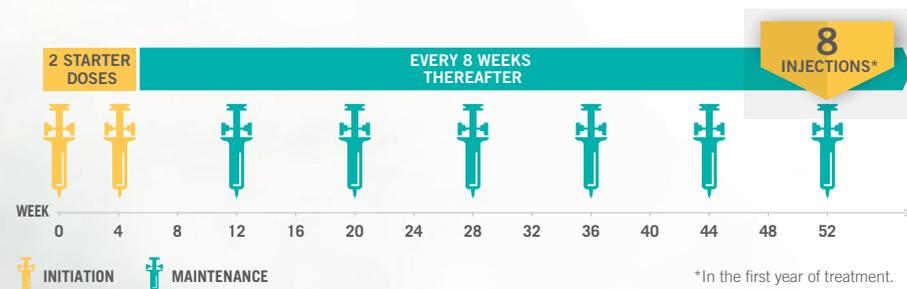
- you have an allergy to the active ingredient in TREMFYA (i.e. guselkumab) or to any of the ingredients listed in the Consumer Medicine Information, available from www.janssen.com.au/tremfya_CMI
 - symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, a tight feeling in your chest, swelling of the face, lips, tongue or other parts of the body.
- the packaging is torn or shows signs of being tampered with
- the expiry date on the pack has passed.

How is TREMFYA given?

TREMFYA is given as a single 100 mg injection under your skin (subcutaneous) via a pre-filled syringe. After your first dose, you will need another dose 4 weeks later (initiation doses). After this second dose, TREMFYA will only need to be given once every 8 weeks (maintenance doses). At the beginning of your treatment, your doctor or nurse may administer TREMFYA injections for you.

Your doctor or nurse may then decide that you or someone close to you can administer TREMFYA without supervision. If your doctor or nurse confirms you are able to self-inject, you will be trained on the correct method of administration. Included within this booklet are instructions on how to self-administer TREMFYA.

Initiation and maintenance dosing



Possible side effects

Just as with all medicines, TREMFYA can have side effects. Some side effects may be serious, but most of the time they are not. Remember that your doctor has weighed the risks of using this medicine against the benefits you are expected to have from TREMFYA.

Listed here are possible side effects you may have while using TREMFYA. Do not be alarmed, you may not experience any of them. Ask your doctor, nurse or pharmacist if you have any questions about TREMFYA or any of the side effects listed here.

Tell your doctor immediately if you experience any of the following side effects:

- cold and/or flu symptoms (upper respiratory infection)
- headache
- joint pain (arthralgia)
- stomach flu (gastroenteritis)
- diarrhoea
- redness at the injection site
- pain at the injection site
- cold sores (herpes simplex infections)
- tinea.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you do not feel well or if you notice any other side effects, even if they are not on this list.

Stop taking TREMFYA and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have any signs of an allergic reaction.

- Symptoms of an allergic reaction may include rash, itching or hives on the skin, shortness of breath, wheezing or difficulty breathing, a tight feeling in your chest, swelling of the face, lips, tongue, or other parts of the body.

Other important information about TREMFYA

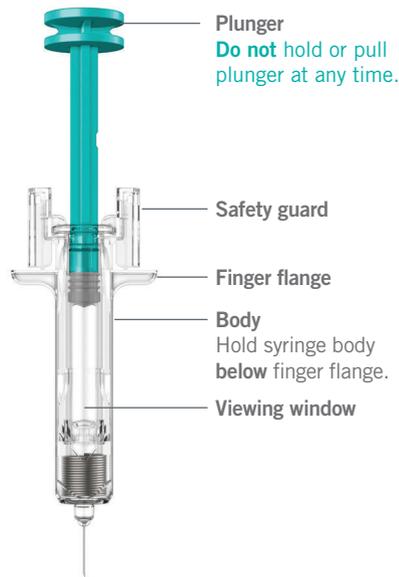
- Tell any other doctors, dentists and pharmacists who are treating you that you are using TREMFYA.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking TREMFYA.
- Tell your doctor, nurse or pharmacist if the medicine starts to upset you or your symptoms become worse.
- Tell your doctor immediately if you develop any symptoms of an infection (see 'Before starting treatment with TREMFYA' on page 11).
- Tell your doctor if you are planning a pregnancy or you become pregnant while using TREMFYA.
- You should also tell your doctor if you plan to breastfeed while using TREMFYA.

For further information, please see the full Consumer Medicine Information available at www.janssen.com.au/tremfya_CMI

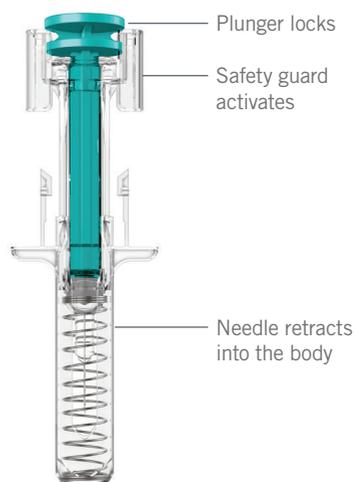
How to self-administer TREMFYA

YOUR PRE-FILLED SAFETY SYRINGE AT-A-GLANCE

Before injection



After injection



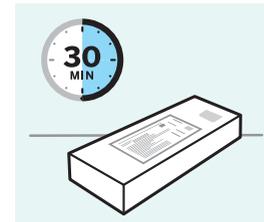
You will need these supplies:

- 1 x alcohol swab
- 1 x cotton ball or gauze pad
- 1 x adhesive bandage
- 1 x sharps container

Storage information

Store in refrigerator at 2°C to 8°C. **Do not freeze.**
Keep TREMFYA pre-filled syringe and all medicines out of reach of children.
Do not shake the pre-filled syringe at any time.
Keep in the original packaging and protect from light.

1 PREPARE FOR YOUR INJECTION



Inspect carton

Remove carton with the pre-filled syringe from the refrigerator. Keep the pre-filled syringe in the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

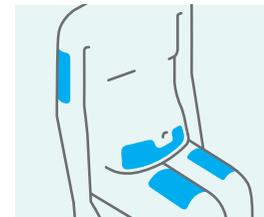
Do not warm any other way.

Check the expiration date ('EXP') on the back panel of the carton.

Do not use if the expiration date has passed.

Do not inject if the perforations on the carton are broken.

Call your doctor or pharmacist for a refill.



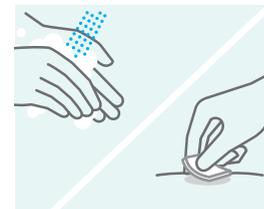
Choose injection site

Select from the following areas for your injection:

- **front of thighs** (recommended)
- lower abdomen (**do not** use the 5-centimetre area around your bellybutton)
- back of upper arms (if a caregiver is giving you the injection).

Do not inject into skin that is tender, bruised, red, scaly or hard.

Do not inject into areas with scars or stretch marks.

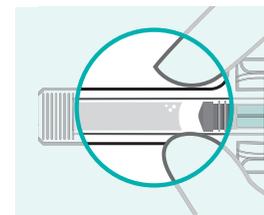


Clean injection site

Wash your hands well with soap and warm water.

Wipe your chosen injection site with an alcohol swab and allow it to dry.

Do not touch, fan or blow on the injection site after you have cleaned it.



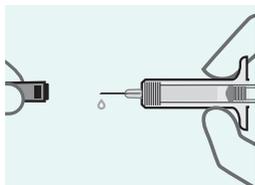
Inspect liquid

Take the pre-filled syringe out of the carton.

Check the liquid in the viewing window. It should be clear to slightly yellow and may contain tiny white or clear particles. You may also see one or more air bubbles. This is normal.

Do not inject if the liquid is cloudy or discoloured, or has large particles. Call your doctor or pharmacist for a refill.

2 INJECT TREMFYA USING PRE-FILLED SYRINGE



Remove needle cover

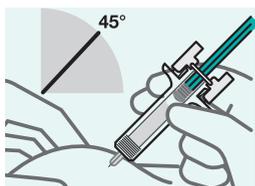
Hold syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

Inject within 5 minutes of removing the needle cover.

Do not put needle cover back on, as this may damage the needle.

Do not touch needle or let it touch any surface.

Do not use the TREMFYA pre-filled syringe if it is dropped. Call your doctor or pharmacist for a refill.



Position fingers and insert needle

Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.

Use your other hand to pinch skin at the injection site.

Position syringe at about a 45 degree angle to the skin.

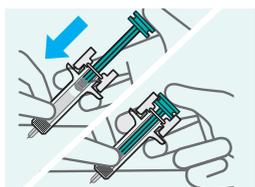
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



Release pinch and reposition hand

Use your free hand to grasp the body of the syringe.



Press plunger

Place thumb from the opposite hand on the plunger and press the plunger all the way down until it stops.



Release pressure from plunger

The safety guard will cover the needle and lock into place, removing the needle from your skin.

3 AFTER YOUR INJECTION



Throw the used pre-filled syringe away

Put your used syringe in a sharps disposal container right away after use.

Make sure you dispose of the bin as instructed by your doctor or nurse when the container is full.



Check injection site

There may be a small amount of blood or liquid at the injection site. Hold pressure over your skin with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site.

If needed, cover injection site with a bandage.

Your injection is now complete.

It is important you do not inject yourself with TREMFYA until you have been trained by a doctor or nurse.
After you have been trained, if you need additional self-injection support, or you have any questions related to the administration of TREMFYA – call the Janssen Immunology Patient Support Program Nurse on 1800 666 845 (see pages 20 and 21) or speak to your doctor, or nurse.



An educational service provided by Janssen-Cilag Pty Ltd.
This booklet is provided as an information resource and is not intended to replace discussions with your healthcare team. If you have any further questions about your condition or treatment, please contact your doctor or nurse.

References: 1. Parisi R *et al.* *J Invest Dermatol* 2013;133:377–385.
2. The Australasian College of Dermatologists. Psoriasis.
<https://www.dermcoll.edu.au/atoz/psoriasis/> (accessed April 2019).



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