▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

TREMFYA®

Guselkumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TREMFYA (pronounced trem-fye-ah). It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using TREMFYA against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What TREMFYA is used for

TREMFYA contains the active substance guselkumab which is a type of protein called a monoclonal antibody. This medicine works by neutralising the activity of a protein called IL-23, which is present in increased levels in people with psoriasis.

TREMFYA is used to treat:

- adults with moderate to severe plaque psoriasis, an inflammatory condition affecting the skin and nails. TREMFYA can improve skin clearance and nail appearance and reduce symptoms of psoriasis, such as scaling, shedding, flaking, itching, pain, and burning.
- adults with active psoriatic arthritis, an inflammatory disease of the joints in which psoriasis usually occurs in association with arthritis. If you have active psoriatic arthritis, you will be given TREMFYA alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (DMARD) such as methotrexate.

Ask your doctor if you have any questions about why TREMFYA has been prescribed for you.

Your doctor may have prescribed TREMFYA for another reason.

Before you use TREMFYA

When you must not use it

Do not use TREMFYA if:

1. **You have an allergy to guselkumab (the active ingredient in the medicine) or to any of the ingredients listed at the end of this leaflet.**

   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.

2. **The packaging is torn or shows signs of tampering.**
3. **The expiry date on the pack has passed.**

Before you start to use it

Tell your doctor 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 with 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

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

TREMFYA may lower your ability to fight infections and may increase your risk of infections.

Do not use TREMFYA if you have any symptoms of infection unless you are instructed to by your doctor.

- have recently had a vaccination or if you are due to have a vaccination during treatment with TREMFYA.

  You should not be given certain types of vaccines (live vaccines) while using TREMFYA.

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

- allergic reactions

  Tell your doctor or get emergency medical help right away if you think you are having an allergic reaction.

- are pregnant or plan to become pregnant.

  The effects of this medicine in pregnant women are not known. Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

  If you are a woman of childbearing potential, use adequate contraception while using TREMFYA and for at least 12 weeks after the last TREMFYA dose. Talk to your doctor about your contraception options.

- are breastfeeding or planning to breastfeed. You and your doctor should decide if you will breastfeed while using TREMFYA.

If you have not told your doctor about any of the above, tell them before you start using TREMFYA.

Your doctor will discuss with you the benefits of using it against the potential risks.

Taking or being given other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

How to use TREMFYA

TREMFYA is only available on prescription.

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

TREMFYA is given by injection under your skin (subcutaneous injection). At the start of your therapy, TREMFYA may be injected by your healthcare provider. Your doctor or nurse may decide that it is right for you to learn how to inject TREMFYA yourself.

It is important not to try to inject yourself until you have been trained by a healthcare professional. If you have not been trained, please contact your healthcare provider to schedule a training session.

A caregiver may also give you your TREMFYA injection after proper training.

Before use, remove the carton from the refrigerator and keep the pre-filled syringe inside the carton and allow to reach room temperature by waiting for 30 minutes.

Read the "Instructions for Use" leaflet for the pre-filled syringe or pre-filled pen carefully before using TREMFYA.

Nurse support is available by calling the Janssen Immunology Patient Support Program on 1800 666 845.

How much to use

Your doctor will decide how much TREMFYA you need and for how long.

For plaque psoriasis

- The first dose is 100 mg (the content of 1 pre-filled syringe or 1 pre-filled pen) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will have the next dose 4 weeks later, and then every 8 weeks. Subsequent doses are the same as the first dose (the content of 1 pre-filled syringe or 1 pre-filled pen).

For psoriatic arthritis

- The first dose is 100 mg (the content of 1 pre-filled syringe or 1 pre filled pen) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will have the next dose 4 weeks later, and then every 8 weeks. Subsequent doses are the same as the first dose (the content of 1 pre-filled syringe or 1 pre-filled pen).
- TREMFYA can be used with or without a type of medicine called a conventional Disease-Modifying Anti-Rheumatic Drug (DMARD), such as methotrexate.

You should not stop using TREMFYA without speaking to your doctor first. If you stop treatment, symptoms of psoriasis may come back.

If you forget to use it

If you forget to take your TREMFYA dose, inject a dose as soon as you remember.

Then, take your next dose at your regular scheduled time

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your pharmacist, nurse or doctor.

If you use too much (overdose)

If you have received more TREMFYA than you should, or

the dose has been given sooner than prescribed, immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Poisons Information Centre telephone number:

- Australia: 13 11 26

While you are using TREMFYA

Things you must do

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 You Use TREMFYA").

Tell your doctor if you become pregnant while using TREMFYA.

Things you must not do

You should not receive a live vaccine while taking TREMFYA. Talk to your doctor, pharmacist or nurse before receiving any vaccination while taking TREMFYA.

Do not give TREMFYA to anyone else, even if they have the same condition as you.

Do not stop using TREMFYA, or change the dose, unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how TREMFYA affects you.

TREMFYA should not affect your ability to drive or use machines. However, make sure you know how you react to it before you do anything that could be dangerous if you feel dizzy.

Side effects

All medicines can have some side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

- cold and/or flu symptoms, chest infection (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
- blood tests may show decreased number of a type of white blood cell called neutrophils or increased level of liver enzymes.

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

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. You need urgent medical attention.

Signs 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.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Ask your doctor, nurse or pharmacist any questions you may have.

How to store TREMFYA

Storage

Store TREMFYA in a refrigerator between 2°C and 8°C.

TREMFYA should not be frozen.

Keep the product in the original carton to protect from light until the time of use.

Do not shake TREMFYA.

Before use, remove the carton from the refrigerator and keep the pre-filled syringe or pre-filled pen inside the carton and allow to reach room temperature by waiting for 30 minutes.

Always keep medicine out of the reach of children.

After using TREMFYA

Disposal

After injecting TREMFYA, place the used syringe or pen immediately into a sharps container. Do not put the used syringe or pen into your normal household or recycling waste.

The syringe or pen should never be re-used. Discard any unused portions of TREMFYA.

If your doctor tells you to stop taking TREMFYA or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

TREMFYA is a clear, colourless to light yellow solution and may contain clear or white particles of protein. This appearance is not unusual for solutions containing proteins.

Do not use TREMFYA if the solution is discoloured, cloudy, or you can see other particulate matter floating in it.

TREMFYA is available as a single use pre-filled syringe or pre-filled pen (One-Press® patient controlled injector) in a carton. Each carton contains 1 pre-filled syringe or 1 pre-filled pen.

An instruction for use leaflet explaining how to self-administer the product is included in the pack.

Do not use TREMFYA if the packaging is torn or shows signs of tampering.

Ingredients

The active ingredient is guselkumab.

The inactive ingredients are histidine, histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection.

No preservatives are present.

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

Australian Registration Number

100 mg pre-filled syringe: AUST R 286020

100 mg pre-filled pen: AUST R 321410

Date of Preparation

May 2022

Nurse and educational support

The Janssen Immunology Patient Support Program is available to patients prescribed TREMFYA. It offers:

- starter kit
- one-to-one nurse support
- reminder service
- ongoing education
- wellbeing support

Call 1800 666 845