TREMFYA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using TREMFYA?

TREMFYA contains the active ingredient guselkumab. TREMFYA is used to treat adults with moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active ulcerative colitis, or moderately to severely active Crohn's disease.
For more information, see Section 1. Why am I using TREMFYA? in the full CMI.

2. What should I know before I use TREMFYA?

Do not use if you have ever had an allergic reaction to guselkumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use TREMFYA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TREMFYA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use TREMFYA?

- TREMFYA is given by injection under your skin (subcutaneous injection) or by infusion given through a vein in your arm (intravenous infusion).

More instructions can be found in Section 4. How do I use TREMFYA? in the full CMI.

5. What should I know while using TREMFYA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using TREMFYA. • Tell your doctor, nurse or pharmacist if the medicine starts to upset you or your symptoms become worse. • Tell your doctor straight away if you develop any symptoms of an infection or allergic reactions. • Keep all your appointments for doctors. • Use appropriate contraception. Tell your doctor if you become pregnant while using TREMFYA.
Things you should not do	• Do not stop using this medicine or change the dose unless your doctor tells you to. • Do not receive a live vaccine while taking TREMFYA.
Driving or using machines	• Be careful before you drive or use any machines until you know how TREMFYA affects you. TREMFYA does not usually affect your ability to drive or use machines
Looking after your medicine	• Store TREMFYA in the refrigerator (between 2°C and 8°C). Do not freeze. • Keep the product in the original carton to protect from light until the time of use. • Do not shake TREMFYA.

For more information, see Section 5. What should I know while using TREMFYA? in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: Signs of an allergic reaction, such as 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; signs of infection such as fever or flu-like symptoms, blood in your phlegm (mucus), muscle aches, cough, shortness of breath, weight loss, stomach flu (gastroenteritis), burning when you urinate or urinating more often than normal, warm, red, or painful skin or sores on your body different from your psoriasis.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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®

Active ingredient(s): *guselkumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TREMFYA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TREMFYA.**

Where to find information in this leaflet:

1. Why am I using TREMFYA?

TREMFYA contains the active ingredient guselkumab. TREMFYA is a type of protein called a monoclonal antibody and works by neutralising the activity of a protein called IL-23, which is present in increased levels in people with psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease.

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.**
- **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.**
- **moderately to severely active ulcerative colitis, an inflammatory disease of the bowel. Using TREMFYA in ulcerative colitis can benefit you by reducing the signs and symptoms of the disease including bloody stools, the need to rush to and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. These effects can enable your normal daily activities and reduce fatigue.**
- **moderately to severely active Crohn's disease, an inflammatory disease of the bowel. Using TREMFYA in Crohn's disease can benefit you by reducing the signs and symptoms of the disease such as diarrhoea, abdominal pain, and the inflammation of your intestinal lining. These effects can enable your normal daily activities and reduce fatigue.**

2. What should I know before I use TREMFYA?

Warnings

Do not use TREMFYA if:

- you are allergic to guselkumab (the active ingredient in the medicine), or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.

Check with 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
  - stomach flu (gastroenteritis)
  - burning when you urinate or urinating more often than normal
  - warm, red, or painful skin or sores on your body different from your psoriasis

  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.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. The effects of this medicine in pregnant women are not known.

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.

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

Children and adolescents

TREMFYA is not recommended for use in children under the age of 18 years. The safety of TREMFYA and how effective it is have not been studied in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TREMFYA.

4. How do I use TREMFYA?

How much / When to use TREMFYA

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.

For moderately to severely active ulcerative colitis

Treatment start:

- The first dose is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm) over at least 1 hour.
- After the first dose, you will have the second dose by intravenous infusion 4 weeks later, and then a third dose by intravenous infusion after an additional 4 weeks.

Maintenance therapy:

A maintenance dose will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 200 mg will be given 4 weeks after the third treatment start dose, and then every 4 weeks.
- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.

For moderately to severely active Crohn's disease

Treatment start:

Treatment start can be given either by intravenous infusion or administered subcutaneously:

Intravenous Infusion:

- The first dose is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm) over at least 1 hour.
- After the first dose, you will have the second dose by intravenous infusion 4 weeks later, and then a third dose by intravenous infusion after an additional 4 weeks.

Subcutaneous administration:

- The first dose is 400 mg and will be given by injections under the skin (subcutaneous) at different locations of the body.
- After the first dose, you will have a second 400 mg dose 4 weeks later and then a third 400 mg dose after an additional 4 weeks.

Maintenance therapy:

A maintenance dose will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 200 mg will be given 4 weeks after the third treatment start dose, and then every 4 weeks.
- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.

How to use TREMFYA

For treatment of plaque psoriasis or psoriatic arthritis, TREMFYA is given by injection under your skin (subcutaneous injection) using a pre-filled syringe or a pre-filled pen (One-Press® patient-controlled injector).

For treatment of ulcerative colitis, the starter doses of TREMFYA will be given through a vein in your arm (intravenous infusion) by your healthcare provider. After completing the starter doses, TREMFYA is given by injection under the skin (subcutaneous injection).

For treatment of Crohn's disease, the starter doses of TREMFYA may be given through a vein in your arm (intravenous infusion) by your healthcare provider or as an

injection under the skin (subcutaneous injection). After completing the starter doses, TREMFYA is given by injection under the 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 or pre-filled pen 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 included in the pack carefully before using TREMFYA.

Educational support

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

- Injection education
- Ongoing medical supplies
- Starter kit
- Reminder service
- Ongoing education

Call 1800 666 845

If you forget to use TREMFYA

If you miss your TREMFYA dose at the usual time, inject a dose as soon as you remember.

Inject your next dose at your next regularly scheduled date. This will put you back on schedule.

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

If you use too much TREMFYA

If you think that you have used too much TREMFYA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using TREMFYA?

Things you should do

- Remind any doctor, dentist or pharmacist you visit 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.
- Keep all your appointments for doctors.

Call your doctor straight away if you:

- Develop any symptoms of an infection (see "What should I know before I use TREMFYA").
- Have allergic reactions (see additional information under Section 6. Are there any side effects?)
- Become pregnant while using TREMFYA

Things you should 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 stop using this medicine or change the dose, unless your doctor tells you to.
- Do not give TREMFYA to anyone else even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- 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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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 you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site: • redness • pain **Skin:** • fungal infection of the skin, for example between the toes (athlete's foot) **Nervous System:** • headache **Joints/Musculoskeletal:** • joint pain (arthralgia)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of an infection: • cold and/or flu symptoms, chest infection (upper respiratory infection) • stomach flu (gastroenteritis) • herpes simplex infections, for example of the lips (cold sores) or genitals (genital herpes)	**Tell your doctor immediately if you experience any of these side effects**
Signs of an allergic reaction: • 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	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TREMFYA contains

Active ingredient (main ingredient)	guselkumab
Other ingredients (inactive ingredients): in Pre-filled syringe or pre-filled pen for subcutaneous injection	histidine, histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injections
Other ingredients (inactive ingredients): in 20 mL Single-dose vial for intravenous infusion (drip through a vein in your arm)	Disodium edetate, histidine, histidine hydrochloride monohydrate, methionine, polysorbate 80, sucrose, and water for injections

No preservatives are present.

Do not take this medicine if you are allergic to any of these ingredients.

What TREMFYA 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 in a carton in the following packaging presentations.

<u>For Subcutaneous Injection</u>

Each carton contains 1 pre-filled syringe or 2 (2 packs of 1) pre-filled syringes:

- 100 mg / 1 mL (100 mg/mL) in a single-dose pre-filled syringe: AUST R 286020
- 200 mg / 2 mL (100 mg/mL) in a single-dose pre-filled syringe: AUST R 460498

Each carton contains 1 pre-filled pen or 2 (2 packs of 1) pre-filled pens:

- 100 mg / 1 mL (100 mg/mL) in a single-dose pre-filled pen (One-Press® patient-controlled injector): AUST R 321410

- 200 mg / 2 mL (100 mg/mL) in a single-dose pre-filled pen (auto-injector): AUST R 460499

For Intravenous Infusion

- 200 mg / 20 mL (10 mg/mL) in a single-dose vial: AUST R 460503 (**only for intravenous infusion** and must only be given by a healthcare provider)

Not all pack sizes may be marketed.

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.

Who distributes TREMFYA

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

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