

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTREMIFYA®
PrTREMIFYA One-Press®
(guselkumab injection)
Solution for injection
100 mg/ 1 mL

Read this carefully before you start taking **TREMIFYA®/TREMIFYA One-Press®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TREMIFYA®/TREMIFYA One-Press®**.

What is TREMIFYA®/TREMIFYA One-Press® used for?

- **Plaque Psoriasis**

TREMIFYA®/TREMIFYA One-Press® is a prescription medicine used to treat adults with moderate to severe “plaque psoriasis”, an inflammatory condition affecting the skin and nails. Plaque psoriasis can cause raised, thick, red and scaly patches (“psoriatic lesions”) that can appear anywhere on your body. TREMIFYA®/TREMIFYA One-Press® reduces the inflammation and other symptoms of the disease.

- **Psoriatic Arthritis**

TREMIFYA®/TREMIFYA One-Press® is used to treat adults with active psoriatic arthritis. Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. Psoriatic arthritis can cause pain, swelling and stiffness in the joints, in addition to a disruption in daily activities and fatigue. If you have active psoriatic arthritis, you will be given TREMIFYA®/TREMIFYA One-Press® alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (cDMARD) such as methotrexate. TREMIFYA®/TREMIFYA One-Press® reduces signs and symptoms of your arthritis and may improve symptoms in patients that have psoriasis.

How does TREMIFYA®/TREMIFYA One-Press® work?

TREMIFYA®/TREMIFYA One-Press® contains the active substance guselkumab. Guselkumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body. This medicine works by neutralizing the activity of a protein called IL-23, which is present at increased levels in diseases such as plaque psoriasis.

Using TREMIFYA®/TREMIFYA One-Press® should improve your skin clearance and reduce your symptoms of psoriasis such as itching, pain, stinging, burning and skin tightness. In addition, TREMIFYA®/TREMIFYA One-Press® helps reduce the signs and symptoms of psoriatic arthritis.

What are the ingredients in TREMIFYA®/TREMIFYA One-Press®?

Medicinal ingredients: guselkumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection.

TREMFYA® comes in the following dosage forms:

100mg/mL solution for injection in a single-dose pre-filled syringe

TREMFYA One-Press® comes in the following dosage forms:

100mg/mL solution for injection in a single-dose patient-controlled injector

Do not use TREMFYA®/TREMFYA One-Press® if:

- You are allergic to guselkumab or any of the ingredients in TREMFYA®/TREMFYA One-Press®. See **What are the ingredients in TREMFYA®/TREMFYA One-Press®**.

If you think you are allergic, ask your healthcare professional for advice before using TREMFYA®/TREMFYA One-Press®.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TREMFYA®/TREMFYA One-Press®. Talk about any health conditions or problems you may have, including if you:

- are being treated for an infection or if you have an infection that does not go away or keeps coming back. TREMFYA®/TREMFYA One-Press® may lower your ability to fight infections and may increase your risk of infections.
- 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
 - muscle aches
 - cough
 - shortness of breath
 - burning when you urinate or urinating more often than normal
 - blood in your phlegm (mucus)
 - weight loss
 - warm, red or painful skin or sores on your body different from your psoriasis
 - diarrhea or stomach pain
- have recently had a vaccination or if you are due to have a vaccination during treatment with TREMFYA®/TREMFYA One-Press®. You should not be given certain types of vaccines (live vaccines) while using TREMFYA®/TREMFYA One-Press®.
- are pregnant, think that you may be pregnant or are planning to have baby. If you are a woman of childbearing potential, use adequate contraception while using TREMFYA®/TREMFYA One-Press® and for at least 12 weeks after the last TREMFYA®/TREMFYA One-Press® dose. Talk to your doctor about your contraception options.
- are breast-feeding or plan to breast-feed. You and your doctor should decide if you will breast-feed while using TREMFYA®/TREMFYA One-Press®.

Look out for infections and allergic reactions

- Do not use TREMFYA®/TREMFYA One-Press® if you have any symptoms of infection unless you are instructed by your healthcare provider.

- **After starting TREMFYA®/TREMFYA One-Press®, call your healthcare provider right away, if you have any of the symptoms of an infection listed above.**
- **Serious allergic reactions, which can include symptoms of a swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, hives and shortness of breath, have occurred with TREMFYA®/TREMFYA One-Press®. Tell your doctor or seek medical help immediately if you experience these symptoms.**

Children and adolescents (below the age of 18 years)

TREMFYA®/TREMFYA One-Press® is not recommended for children and adolescents (under 18 years of age) because it has not been studied in this age group.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take TREMFYA®/TREMFYA One-Press®:

Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

TREMFYA®/TREMFYA One-Press® is given by injection under your skin (subcutaneous injection).

You and your healthcare professional should decide if you should inject TREMFYA®/TREMFYA One-Press® yourself. It is important not to try to inject yourself until you have been trained by your healthcare professional. A caregiver may also give you your TREMFYA®/TREMFYA One-Press® injection after proper training.

Before use, remove TREMFYA®/TREMFYA One-Press® from the refrigerator. Keep TREMFYA®/TREMFYA One-Press® inside the carton and allow it to reach room temperature by waiting for 30 minutes before injection.

Read the “Instructions for Use” document carefully before using TREMFYA®/TREMFYA One-Press®.

Usual dose:

Your doctor will decide how much TREMFYA®/TREMFYA One-Press® you need and for how long.

Plaque Psoriasis

- The dose is 100 mg (the contents of 1 pre-filled syringe or the contents of 1 patient-controlled injector) by subcutaneous injection.
- The first dose may be given by your healthcare provider.
- After the first dose, you will have the next dose 4 weeks later, and then every 8 weeks.

Psoriatic Arthritis

- The dose is 100 mg (the contents of 1 pre-filled syringe or the contents of 1 patient-controlled injector) by subcutaneous injection.
- The first dose may be given by your healthcare provider.
- After the first dose, you will have the next dose 4 weeks later, and then every 8 weeks

TREMFYA®/TREMFYA One-Press® is for long-term treatment. Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

You should not stop using TREMFYA®/TREMFYA One-Press® unless you think it is causing a severe side effect. Speak to your doctor as soon as possible if this happens.

Overdose:

If you accidentally inject more TREMFYA®/TREMFYA One-Press® than you should or the dose has been given sooner than prescribed, inform your healthcare professional.

If you think you have taken too much TREMFYA®/TREMFYA One-Press®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take your TREMFYA®/TREMFYA One-Press® dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. If you are not sure what to do, contact your healthcare professional.

What are possible side effects from using TREMFYA®/TREMFYA One-Press®?

As with all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the following side effects are mild to moderate. If any of these side effects becomes severe, tell your healthcare professional.

Some side effects are very common (may affect more than 1 in 10 people)

- Infections of the nose, sinuses, or throat (e.g. common cold) or chest infections (bronchitis)

Some side effects are common (may affect up to 1 in 10 people):

- Redness, pain, irritation, swelling, bruising and/or itching at the injection site
- diarrhea
- headache
- joint pain
- increased level of liver enzymes in the blood

Some side effects are uncommon (may affect up to 1 in 100 people):

- stomach flu (gastroenteritis)
- herpes simplex infections (e.g. cold sores, genital herpes)
- fungal infections of the skin (e.g. athlete's foot)
- migraine
- yeast infections
- allergic reactions
- skin rash
- decreased number of a type of white blood cell called neutrophils

These are not all the possible side effects you may feel when taking TREMFYA®/TREMFYA One-Press®. If you experience any side effects not listed here, contact your healthcare professional.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store TREMFYA®/TREMFYA One-Press® in the refrigerator between 2°C to 8°C (36°F to 46°F).

Do not freeze. Do not use if TREMFYA®/TREMFYA One-Press® has been frozen.

Do not shake TREMFYA®/TREMFYA One-Press®.

Store in original packaging to protect from light until use.

Keep out of reach and sight of children.

Do not use TREMFYA®/TREMFYA One-Press®:

- if you notice that it is damaged or the seal is broken.
- if the liquid is discoloured, cloudy or you can see large particles floating in it.
- after the expiry date which is stated on the label and on the outer carton after “EXP.”

TREMFYA®/TREMFYA One-Press® is for single use only. Ask your healthcare professional how to throw away medicines no longer required.

If you want more information about TREMFYA®/TREMFYA One-Press®:

- Talk to your healthcare professional
- For questions or concerns, contact the manufacturer, Janssen Inc. (www.janssen.com/canada)
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>; the manufacturer's website www.janssen.com/canada, or by contacting the manufacturer at: 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario, M3C 1L9.

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