PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

\[
\text{TREMFYA®} \\
\text{TREMFYA One-Press®} \\
(\text{guselkumab injection}) \\
\text{Solution for injection} \\
100 \text{ mg/ 1 mL}
\]

Read this carefully before you start taking TREMFYA®/TREMFYA 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 TREMFYA®/TREMFYA One-Press®.

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

- **Plaque Psoriasis**
  TREMFYA®/TREMFYA 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. TREMFYA®/TREMFYA One-Press® reduces the inflammation and other symptoms of the disease.

- **Psoriatic Arthritis**
  TREMFYA®/TREMFYA 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 TREMFYA®/TREMFYA One-Press® alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (cDMARD) such as methotrexate. TREMFYA®/TREMFYA One-Press® reduces signs and symptoms of your arthritis and may improve symptoms in patients that have psoriasis.

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

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

What are the ingredients in TREMFYA®/TREMFYA 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.

TREMФYA®/TREMФYA 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®/TREMФYA 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®/TREMФYA 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®/TREMФYA 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®/TREMФYA 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®/TREMФYA 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.

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**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.*

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**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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INSTRUCTIONS FOR USE (TREMFYA®)

P-TREMFYA®
(guselkumab injection)
Pre-filled syringe

PLEASE READ THESE INSTRUCTIONS BEFORE USE
Important

TREMFYA® comes as a single-dose pre-filled syringe containing one 100 mg dose. Each pre-filled syringe can be used only one time. Throw the used pre-filled syringe away (see Step 3) after each dose, even if there is medicine left in it. Do not reuse your pre-filled syringe.
If your doctor decides that you or a caregiver may be able to give your injections of TREMFYA® at home, you should receive training on the right way to prepare and inject TREMFYA® using the pre-filled syringe before attempting to inject.
Read this Instructions for Use document before using the TREMFYA® pre-filled syringe and each time you get a refill. There may be new information. This instruction guide does not take the place of talking with your doctor about your medical condition or your treatment. Please also read the Package Insert carefully and discuss any questions you may have with your doctor or nurse.
The TREMFYA® pre-filled syringe is intended for injection under the skin, not into the muscle or vein. After injection, the needle will retract into the body of the device and lock into place.

Storage information
Store in refrigerator at 2° to 8°C. Do not freeze.

Keep TREMFYA® and all medicines out of reach and sight of children.

Do not shake the pre-filled syringe.
Keep TREMFYA® pre-filled syringe in the original carton to protect from light and physical damage.

Pre-filled syringe parts

Before injection

- **Plunger**  
  Do not hold or pull plunger at any time.

- **Safety guard**

- **Finger flange**

- **Body**  
  Hold syringe body below finger flange.

- **Viewing window**

- **Needle cover**  
  Do not remove until you are ready to inject TREMFYA® (See Step 2).
After injection

- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Adhesive bandage
- 1 Sharps container (See Step 3)
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 TREMFYA® 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 2-inch (5-centimetre) area around belly-button.
- 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 discolored, or has large particles. Call your doctor or pharmacist for a refill.
2. Inject TREMFYA® using the 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
or cause a needle stick injury.
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.
Do not dispose in your household trash.
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.

Need Help?
Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer’s website www.janssen.com/canada, or call 1-800-567-3331 or 1-800-387-8781.

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

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INSTRUCTIONS FOR USE (TREMFYA One-Press®)

(TREMFYA One-Press®
(guselkumab injection)

patient-controlled injector

Important
TREMFYA One-Press® comes as a single-dose patient-controlled injector containing one 100 mg dose. Each One-Press injector can only be used one time. Throw away (see Step 3) after each dose, even if there is medicine left in it. Do not reuse your One-Press injector.
If your doctor decides that you or a caregiver may be able to give your injections of TREMFYA One-Press® at home, you should receive training on the right way to prepare and inject TREMFYA One-Press®.
Please read these Instructions for use before using the TREMFYA One-Press® and each time you fill your prescription. There may be new information. This instruction guide does not take the place of talking with your doctor about your medical condition or your treatment.
Please also read the Package Insert carefully before starting your injection and discuss any questions you may have with your doctor or nurse.

Storage information
Store in refrigerator at 2° to 8°C. Do not freeze.

Keep TREMFYA One-Press® and all medicines out of reach and sight of children.

Do not shake at any time.
Keep TREMFYA One-Press® in the original carton to protect from light and physical damage.
You will need these supplies:

- 1 Alcohol swab
- 1 Cotton ball or gauze pad
- 1 Adhesive bandage
- 1 Sharps container (See Step 3)
1. Prepare for your injection

Inspect carton
Remove carton with TREMFYA One-Press® from the refrigerator. Keep TREMFYA One-Press® 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 carton.
Do not use if the expiration date has passed.
Do not inject if perforations on the carton are broken.
Call your doctor or pharmacist for a new TREMFYA One-Press®.

Choose injection site
Select from the following areas for your injection:
• Front of thighs (recommended)
• Lower abdomen
  Do not use the 2-inch (5-centimetre) area around your belly-button.
• Back of upper arms (if a caregiver is giving you the injection)
Do not inject into skin that is tender, bruised, red, scaly, hard or has scars or stretch marks.
Wash hands
Wash your hands well with soap and warm water.

Clean injection site
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 in window
Take TREMFYA One-Press® out of the carton.
Check the liquid in the 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. If you are uncertain, call your doctor or pharmacist for a new TREMFYA One-Press®.
2. Inject TREMFYA One-Press® using the patient-controlled injector

Twist and pull off bottom cap
Keep hands away from the needle guard after the cap is removed.
**Inject within 5 minutes of removing the cap.**
**Do not** put the cap back on, this could damage the needle.
**Do not** use the product if it is dropped after removing the cap.
Call your doctor or pharmacist for a new TREMFYA One-Press®.

Place on skin
Position TREMFYA One-Press® straight onto the skin (about 90 degrees relative to injection site).

Push handle straight down
Medication injects as you push. Do this at a speed that is comfortable for you. Do not lift **TREMFYA One-Press** during the injection. The needle guard will lock and the full dose will not be delivered.

**Complete injection**
Injection is complete when the handle is pushed all the way down, you hear a click, and the teal body is no longer visible.

**Lift straight up**
The yellow band indicates that the needle guard is locked.

### 3. After your injection

**Throw the used product away**
Put your used product 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.

**Need Help?**
Call your doctor to talk about any questions you may have. For questions or concerns visit the manufacturer’s website www.janssen.com/canada, or call 1-800-567-3331 or 1-800-387-8781.

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