READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrTREMFLYA™
PrTREMFLYA One-Press™
(guselkumab injection)
Solution for injection
100 mg/ 1 mL

Read this carefully before you start taking TREMFLYA™/TREMFLYA 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 TREMFLYA™/TREMFLYA One-Press™.

What is TREMFLYA™/TREMFLYA One-Press™ used for?
TREMFLYA™/TREMFLYA 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. TREMFLYA™/TREMFLYA One-Press™ reduces the inflammation and other symptoms of the disease.

How does TREMFLYA™/TREMFLYA One-Press™ work?
TREMFLYA™/TREMFLYA 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 TREMFLYA™/TREMFLYA One-Press™ should improve your skin clearance and reduce your symptoms of psoriasis such as itching, pain, stinging, burning and skin tightness.

What are the ingredients in TREMFLYA™/TREMFLYA One-Press™?
Medicinal ingredients: guselkumab
Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, sucrose, polysorbate 80 and water for injection.

TREMFLYA™ comes in the following dosage forms:
100mg/mL solution for injection in a single-dose pre-filled syringe

TREMFLYA One-Press™ comes in the following dosage forms:
100mg/mL solution for injection in a single-dose patient-controlled injector

Do not use TREMFLYA™/TREMFLYA One-Press™ if:
• You are allergic to guselkumab or any of the ingredients in TREMFLYA™/TREMFLYA One-Press™. See What are the ingredients in TREMFLYA™/TREMFLYA 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 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.

- 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)

Some side effects are common (may affect up to 1 in 10 people):
• Redness, pain, swelling, bruising and/or itching at the injection site
• stomach flu (gastroenteritis)
• diarrhea
• headache
• joint pain
• fungal infections of the skin (e.g. athlete’s foot)
• herpes simplex infections (e.g. cold sores, genital herpes)

Some side effects are uncommon (may affect up to 1 in 100 people):
• migraine
• yeast infections
• allergic reactions
• skin rash

These are not all the possible side effects you may feel when taking TREMFYA™. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Warnings and Precautions**.

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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**
- Online at MedEffect® (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect® (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting).

*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 TREMFIYA™/TREMFYA One-Press™ in the refrigerator between 2°C to 8°C (36°F to 46°F)

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

Do not shake TREMFIYA™/TREMFYA One-Press™.

Store in original packaging to protect from light until use.

Keep out of reach and sight of children.

**Do not use TREMFIYA™/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.”

TREMFIYA™/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 TREMFIYA™/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 http://hc-sc.gc.ca/index-eng.php; the manufacturer’s website www.janssen.com/canada, or by contacting the manufacturer at: 1-800-567-3331 or 1-800-387-8781.
INSTRUCTIONS FOR USE

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

- Plunger locks
- Safety guard activates
- Needle retracts into the body

You will need these additional 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 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.
INSTRUCTIONS FOR USE

PrTREMFYA 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 of children.
**Do not** shake at any time.
Keep TREMFYA One-Press™ in the original carton to protect from light and physical damage.

**TREMFYA One-Press™ at-a-glance**

- Handle
- Teal Body
- Window
- Needle Guard
- Bottom Cap

**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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