

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

**TREMFYA™
(guselkumab)
Solution for injection
100 mg/mL**

Read this carefully before you start taking **TREMFYA™** 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™**.

What is TREMFYA™ used for?

TREMFYA™ 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™ reduces the inflammation and other symptoms of the disease.

How does TREMFYA™ work?

TREMFYA™ 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™ 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 TREMFYA™?

Medicinal ingredients: guselkumab

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

TREMFYA™ comes in the following dosage forms:

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

Do not use TREMFYA™ if:

- You are allergic to guselkumab or any of the ingredients in TREMFYA™. See **What are the ingredients in TREMFYA™**.

If you think you are allergic, ask your healthcare professional for advice before using TREMFYA™.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TREMFYA™. 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™ 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™. You should not be given certain types of vaccines (live vaccines) while using TREMFYA™.
- 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™ and for at least 12 weeks after the last TREMFYA™ 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™.

Look out for infections and allergic reactions

- Do not use TREMFYA™ if you have any symptoms of infection unless you are instructed by your healthcare provider.
- **After starting TREMFYA™, 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™. Tell your doctor or seek medical help immediately if you experience these symptoms.**

Children and adolescents (below the age of 18 years)

TREMFYA™ 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™:

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

TREMFYA™ is given by injection under your skin (subcutaneous injection).

You and your healthcare professional should decide if you should inject TREMFYA™ 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™ injection after proper training.

Before use, remove the carton from the refrigerator. Keep the pre-filled syringe 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™.**Usual dose:**

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

- The dose is 100 mg (the content of 1 pre-filled syringe) 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™ 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™ 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™ 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™, 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™ 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™?

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 TREMFYA™ in the refrigerator between 2°C to 8°C (36°F to 46°F)

Do not freeze. Do not use if TREMFYA™ has been frozen.

Do not shake TREMFYA™.

Store in original packaging to protect from light until use.

Keep out of reach and sight of children.

Do not use TREMFYA™:

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

This medicine is for single use only. Ask your healthcare professional how to throw away medicines no longer required.

If you want more information about TREMFYA™:

- 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.

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

Last Revised: October 2018

© 2018 JANSSEN Inc.

All trademarks used under license.

INSTRUCTIONS FOR USE

TREMFYA™ (guselkumab) Pre-filled syringe



SINGLE-DOSE

PLEASE READ THESE INSTRUCTIONS BEFORE USE

Important

TREMFYA™ comes as a single-use 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.

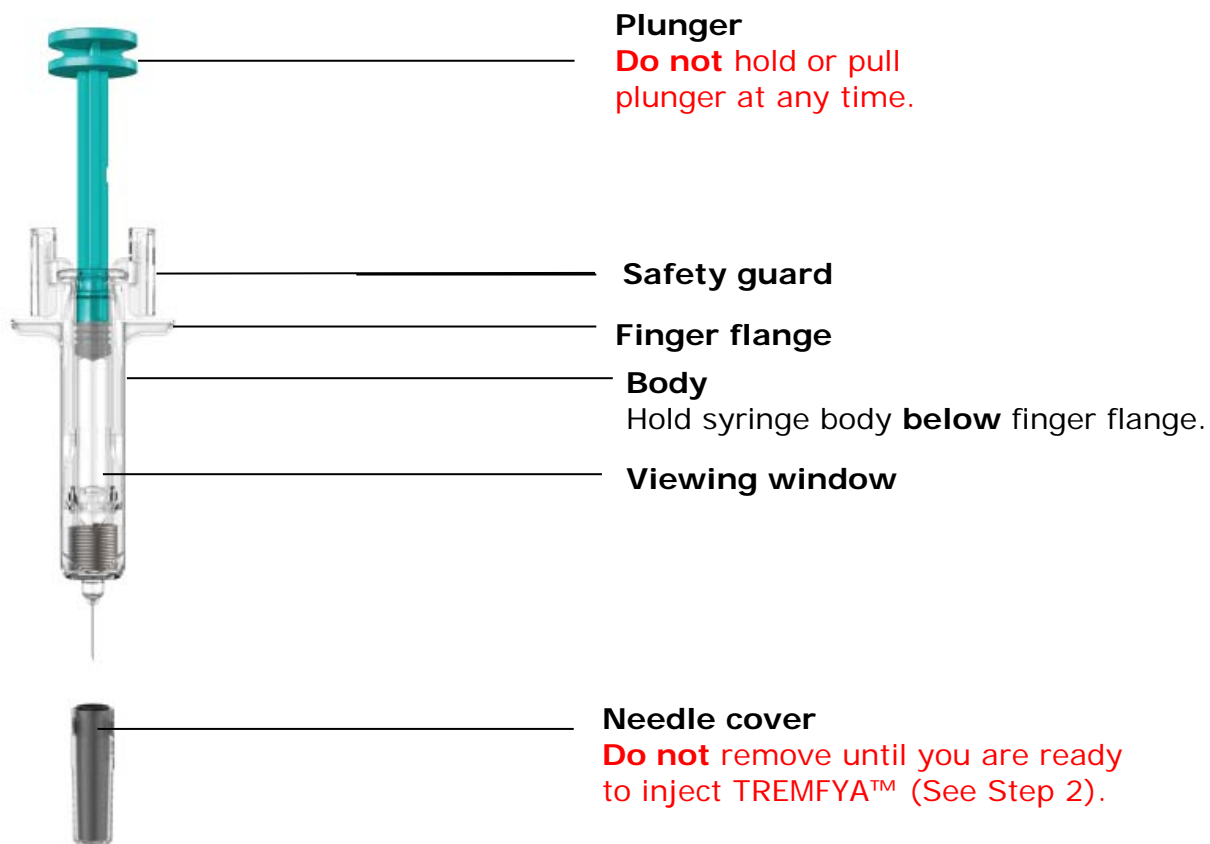
Keep TREMFYA™ and all medicines out of reach and sight of children.

Do not shake the pre-filled syringe.

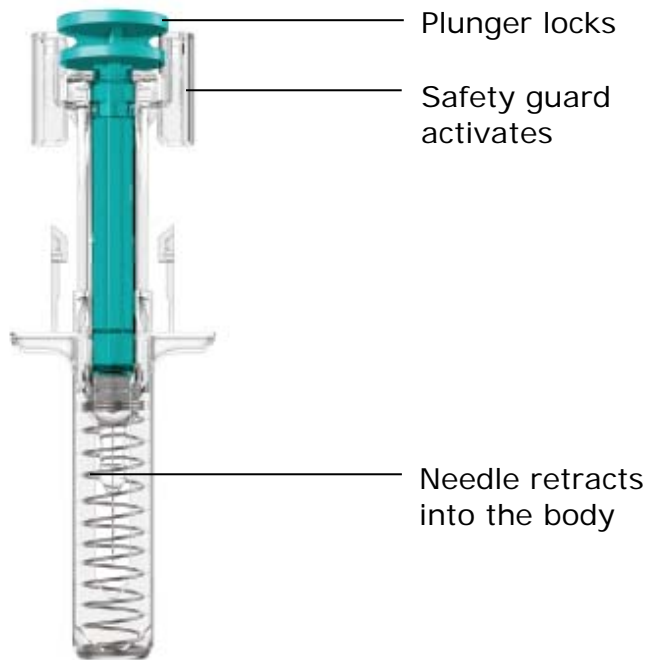
Keep TREMFYA™ pre-filled syringe in the original carton to protect from light and physical damage.

Pre-filled syringe parts

Before injection



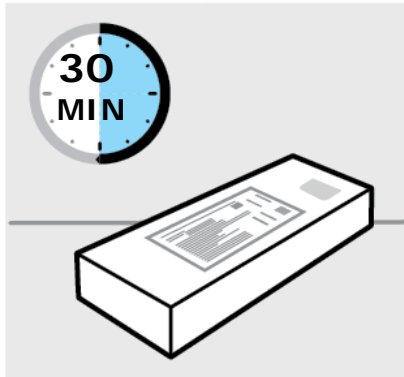
After injection



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.



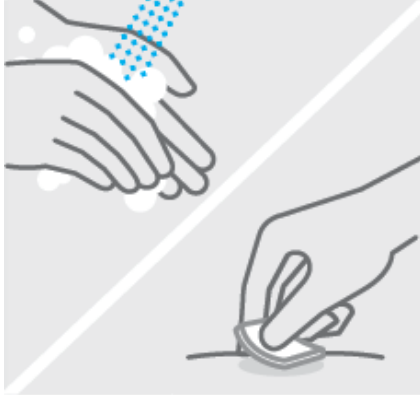
Choose injection site

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.

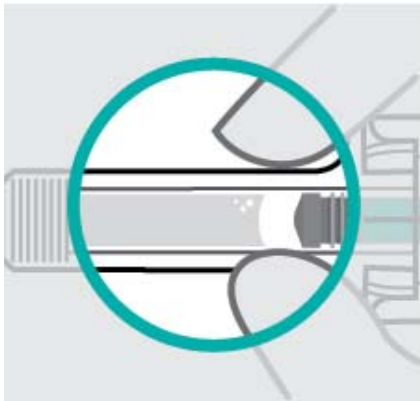


Clean injection site

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.



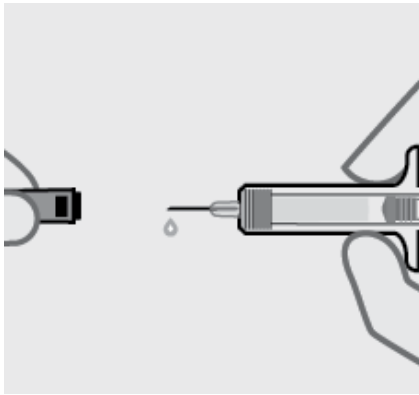
Inspect liquid

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

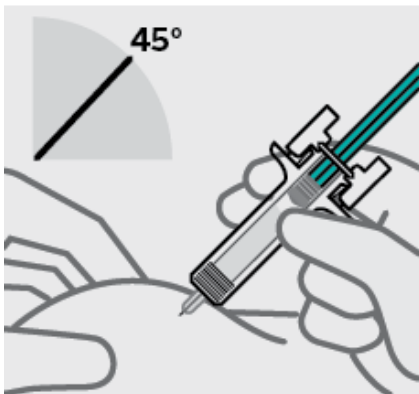
Hold syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

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

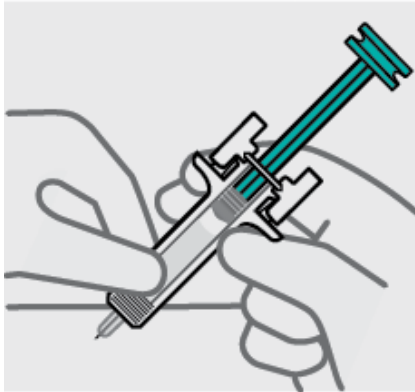
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

Do not touch plunger or area above finger flange as this may cause the needle safety device to activate.

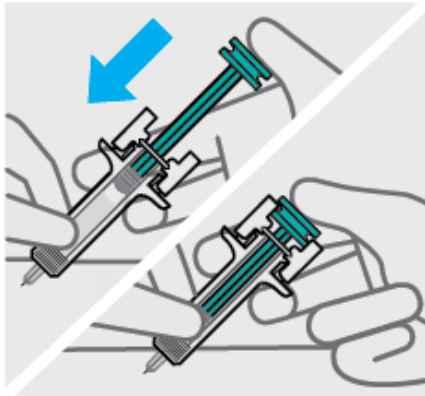
Use your other hand to pinch skin at the injection site. Position syringe at about a 45 degree angle to the skin.

It is important to pinch enough skin to **inject under**

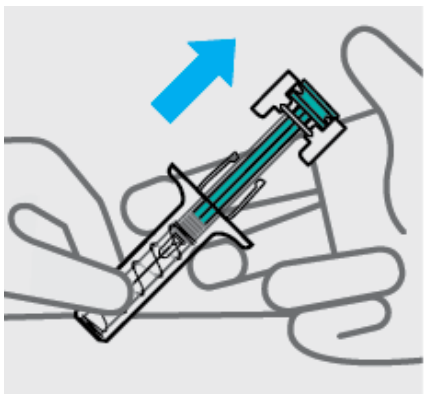
the skin and not into the muscle.
Insert needle with a quick, dart-like motion.



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

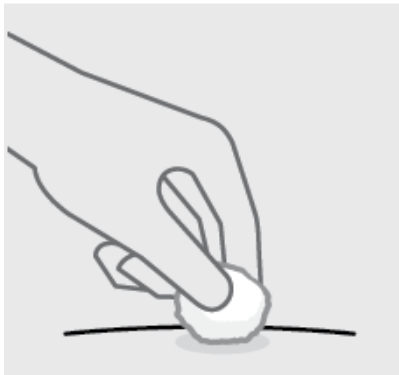


Throw the used pre-filled syringe away

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.

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

Last Revised: October 2018

All trademarks used under license.