

TREMFYA (Guselkumab)

Read all of this package insert carefully before you start taking this medicine.

- Keep this package insert. You may need to read it again.
- If you have any questions, ask your doctor or nurse.

What is in this package insert

1. What TREMFYA is and what it is used for
2. What you need to know before you use TREMFYA
3. How to use TREMFYA
4. What are the possible side effects of TREMFYA
5. How to store TREMFYA
6. Contents of the pack and other information

1. What TREMFYA is and what it is used for

TREMFYA contains the active substance guselkumab which is a type of protein called a monoclonal antibody. This medicine works by neutralizing the activity of a protein called IL-23, which is present at increased levels in people with psoriasis.

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.

2. What you need to know before you use TREMFYA

Warnings and Precautions

Talk to your doctor, pharmacist or nurse, before taking TREMFYA.

If you think you may be allergic to guselkumab or any other ingredients of this medicine, ask your doctor for advice before using TREMFYA.

Infections

Before starting TREMFYA, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or that 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
 - muscle aches
 - cough
 - shortness of breath
 - burning when you urinate or urinating more often than normal
 - blood in your phlegm (mucus)

- weight loss
- diarrhea or stomach pain
- warm, red, or painful skin or sores on your body different from your psoriasis

After starting TREMFYA, call your healthcare provider right away if you have any of the symptoms of infection listed above.

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 healthcare provider.

Vaccinations

Tell your doctor if you 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.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using TREMFYA.

Allergic reactions

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. Tell your doctor or get emergency medical help right away if you think you are having an allergic reaction.

Children and adolescents

TREMFYA is not recommended for children and adolescents under 18 years of age because it has not been studied in this age group.

Other medicines and TREMFYA

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Pregnancy

The effects of this medicine in pregnant women are not known. Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

Contraception

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.

Breast-feeding

Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you will breast-feed while using TREMFYA.

3. How to use TREMFYA

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor, nurse or pharmacist if you are not sure.

TREMFYA is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject TREMFYA yourself.

It is important not to try to inject yourself until you have been trained by your doctor or nurse. 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 inside the carton and allow to reach room temperature by waiting for 30 minutes. Read the “Instructions for Use” for the syringe carefully before using TREMFYA.

How much TREMFYA is given and for how long

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

- The first dose is 100 mg (the content of 1 pre-filled syringe) 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. The following doses are the same as the first dose.

If you use more TREMFYA than you should

If you have received more TREMFYA than you should or the dose has been given sooner than prescribed, inform your doctor.

If you forget to use TREMFYA

If you have forgotten to inject a dose of TREMFYA, inform your doctor.

If you stop using TREMFYA

You should not stop using TREMFYA without speaking to your doctor first. If you stop treatment, symptoms of psoriasis may come back.

4. What are the possible side effects of TREMFYA

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

Side effects:

- Infections of the nose, sinuses or throat (common cold), chest infection
- stomach flu (gastroenteritis)
- fungal infection of the skin, for example between the toes (athlete’s foot)

- herpes simplex infections, for example of the lips (cold sores) or genitals (genital herpes)
- headache
- diarrhea
- joint pain
- redness, pain and irritation at the injection site
- allergic reaction
- skin rash
- hives
- decreased number of a type of white blood cell called neutrophils
- increased level of liver enzymes in the blood

These are not all of the side effects with TREMFYA. Tell your doctor about any side effect that bothers you or does not go away.

General information about TREMFYA

Do not use TREMFYA for a condition for which it was not prescribed.

5. How to store TREMFYA

If you are using TREMFYA at home, it is important to store the product in your refrigerator although not in the freezer compartment. TREMFYA should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

This medicine is for single use only. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

What are the ingredients in TREMFYA?

The active ingredient is guselkumab.

TREMFYA 100 mg for subcutaneous (under the skin) injection. The inactive ingredients include: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

6. Contents of the pack and other information

TREMFYA 100 mg solution for subcutaneous injection is a clear, colorless to light yellow solution and may contain clear or white particles of protein. This appearance is not unusual for solutions containing protein.

TREMFYA is available as:

- 100 mg (100 mg/mL in 1.0 mL syringe volume)

TREMFYA is available in the following packaging presentation:

- 1 single-use pre-filled syringe in a passive needle guard delivery system.

TREMFYA should not be used:

- after the expiration date on the label;
- if the seal is broken;
- if the liquid is discolored, cloudy or you can see other particulate matter floating in it.

Always keep medicine out of the sight and reach of children.

How to Dispose of TREMFYA

Used syringes should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your state or local regulations. Antiseptic wipes, and other supplies can be placed in your regular trash. The syringe must never be re-used. Discard any unused portion of TREMFYA.

Instructions for Injecting TREMFYA under the skin yourself

At the start of your therapy, TREMFYA may be injected by your healthcare provider. However, your healthcare provider may decide that it is right for you or your caregiver to learn how to inject TREMFYA under the skin (subcutaneously) yourself. **Before you self-inject TREMFYA, you must be trained by a healthcare professional. If you have not been trained, please contact your healthcare provider to schedule a training session.** Call your healthcare provider if you have any questions about giving yourself an injection.

This information sheet summarizes the most important information about TREMFYA. You can ask your healthcare provider for information about TREMFYA that is written for healthcare professionals.

Instructions for Use (Pre-filled Syringe)



SINGLE-USE DEVICE

Important

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.

Please read this Instructions for Use 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 Leaflet and instructions for administration carefully before starting your injection 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

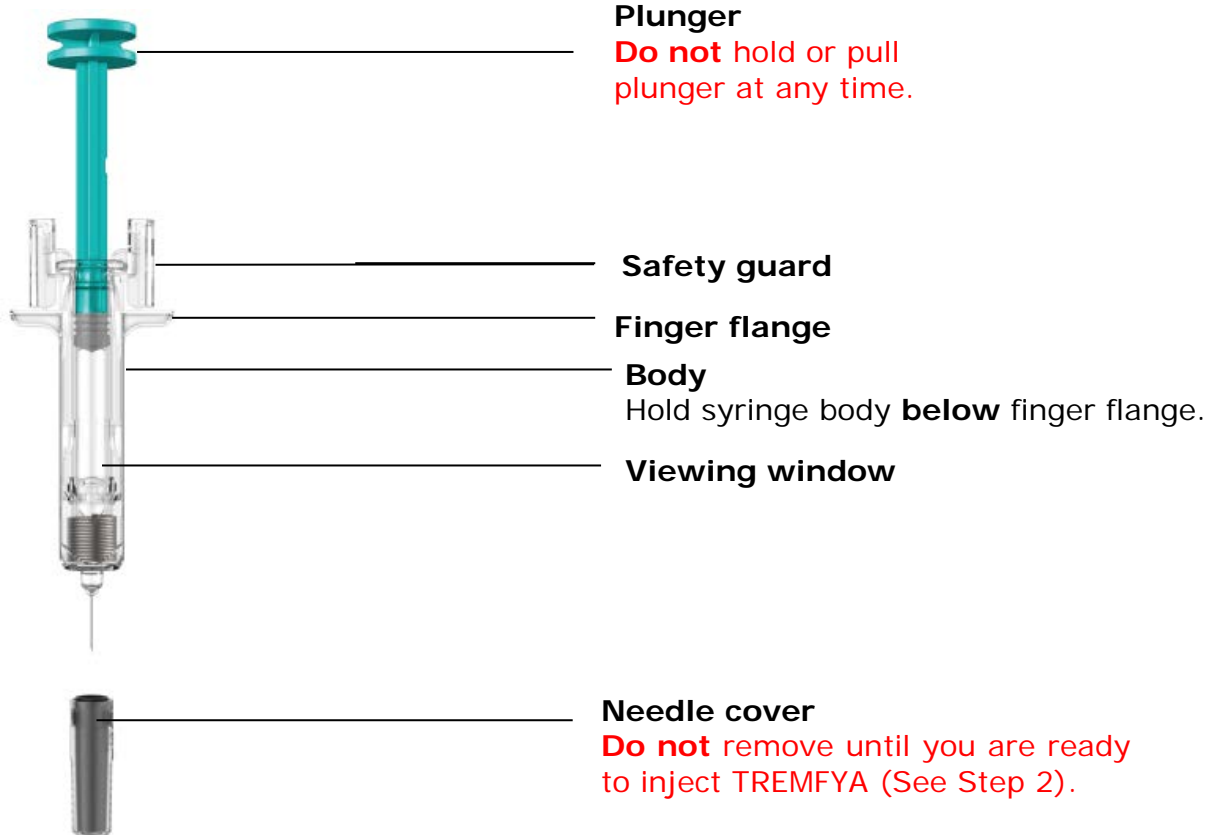
Store in refrigerator at 2° to 8°C. **Do not** freeze.

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

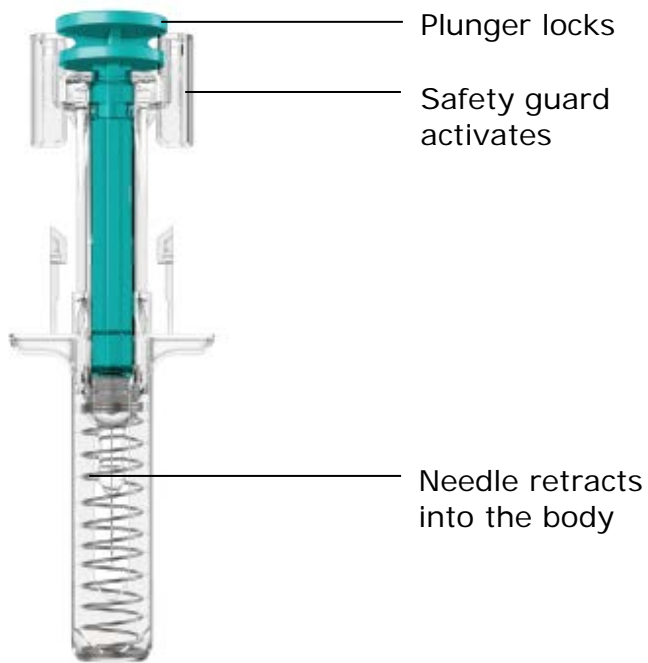
Do not shake the pre-filled syringe at any time.

Pre-filled syringe at-a-glance

Before injection



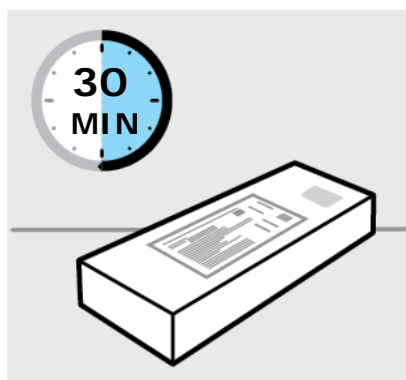
After injection



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 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 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.

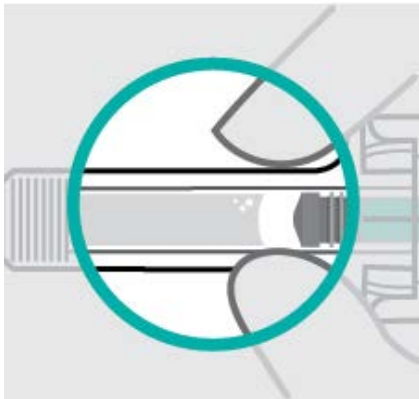


Clean injection site

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.



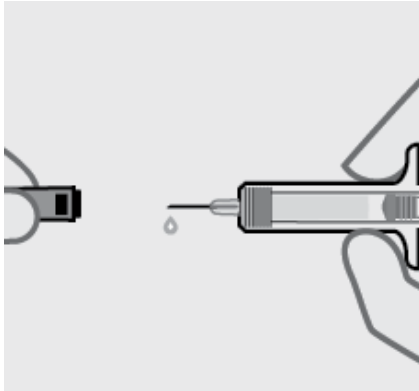
Inspect liquid

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. If you are uncertain, call your doctor or pharmacist for a refill.

2. Inject TREMFYA using the pre-filled syringe



Remove needle cover

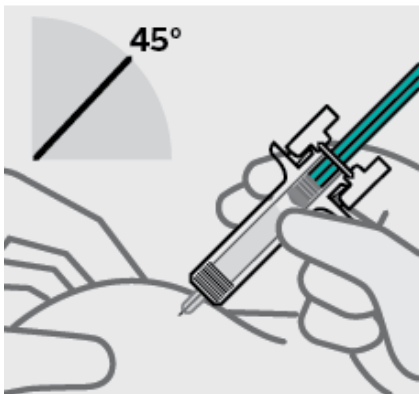
Hold syringe by the body and pull needle cover straight off. It is normal to see a drop of liquid.

Inject within 5 minutes of removing the needle cover.

DO NOT put needle cover back on, as this may damage the needle.

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

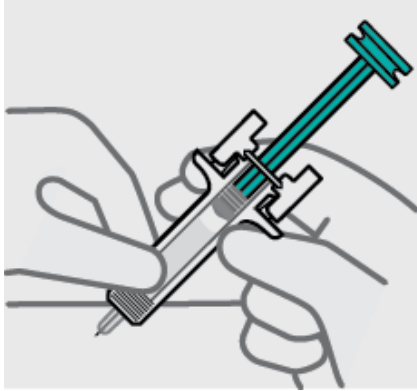
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

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.

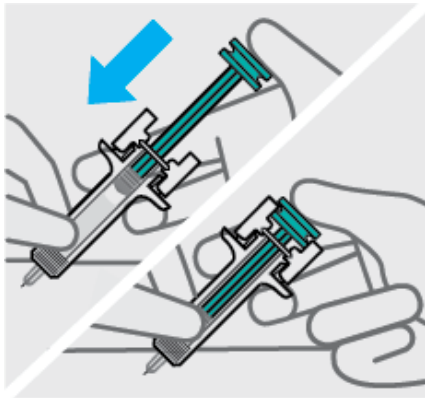
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



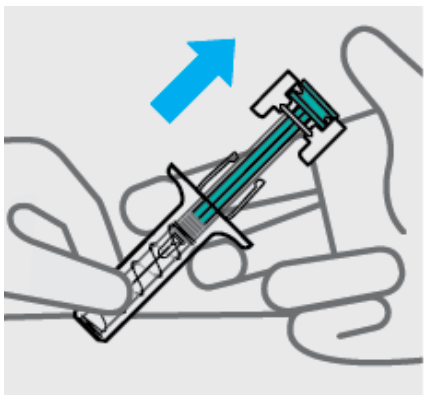
Release pinch and reposition hand

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.

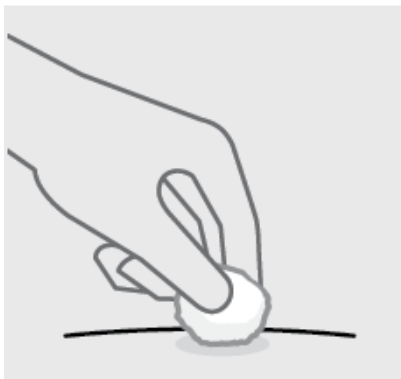
3. After your injection



Throw the used pre-filled syringe away

Put your used syringe in a sharps disposal container right away after use.

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.

Your injection is now complete!

Pre-filled Syringe IFU issued: Nov 2016

BATCH RELEASER

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