

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.
- adults with active psoriatic arthritis, an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given TREMFYA® alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug (DMARD) such as methotrexate.
- adults with moderate to severe palmoplantar pustulosis (PPP), an inflammatory condition causing redness and pustules affecting the palms of the hands and/or soles of the feet.

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 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 pen inside the carton and allow to reach room temperature by waiting for 30 minutes. Read the “Instructions for Use” for the pre-filled pen 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.

For plaque psoriasis:

- The first dose is 100 mg (the content of 1 pre-filled pen) 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.

For psoriatic arthritis:

- The first dose is 100 mg (the content of 1 pre-filled pen) 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. For some patients, after the first dose, Tremfya[®] may be given every 4 weeks. Your doctor will decide how often you may receive Tremfya[®].

For palmoplantar pustulosis:

- The first dose is 100 mg (the content of 1 pre-filled pen) 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, your symptoms 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 pen with a passive needle guard.

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 pre-filled pens 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 pre-filled pen 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.

Instruction for use (Pre-filled Pen)



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 pen.

Please read these “Instructions for use” before using the TREMFYA® pre-filled pen and each time you get a new pre-filled pen. 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 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 (36° to 46°F).

Do not freeze.

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

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



Need help?

Call your doctor to talk about any questions you may have. For additional assistance or to share your feedback refer to the Package Leaflet for your local representative contact information.

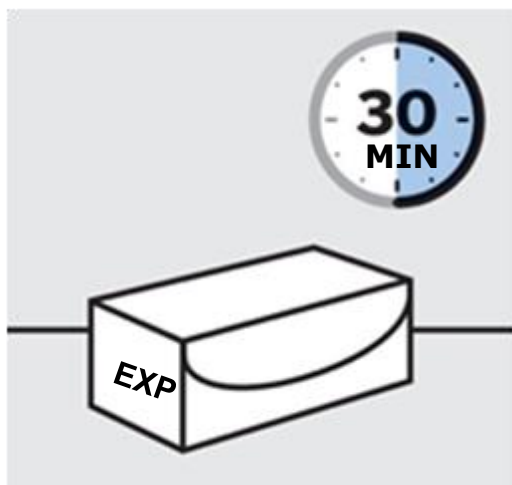
Pre-filled pen at-a-glance



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 pen from the refrigerator.

Keep pre-filled pen in the carton and let it sit on a flat surface at room temperature for **at least 30 minutes** before use.

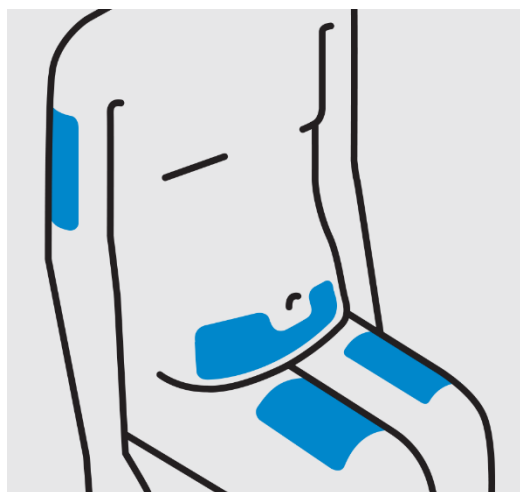
Do not warm any other way.

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 pre-filled pen.



Choose injection site

Select from the following areas for your injection:

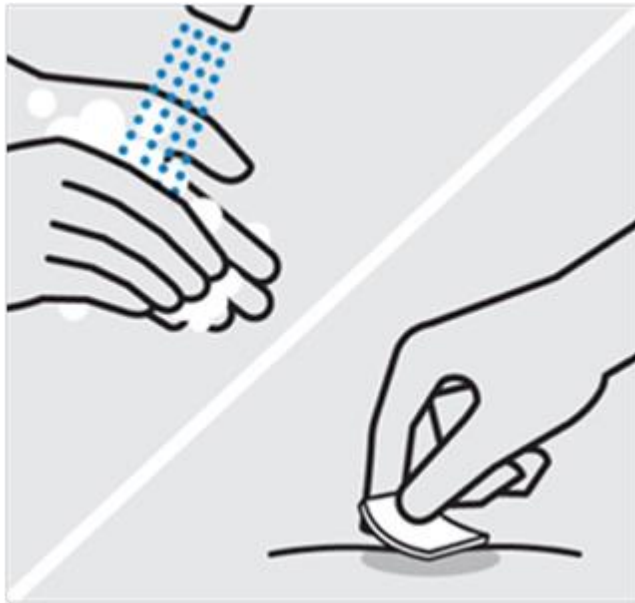
- **Front of thighs** (recommended)

- Lower abdomen

Do not use the 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.



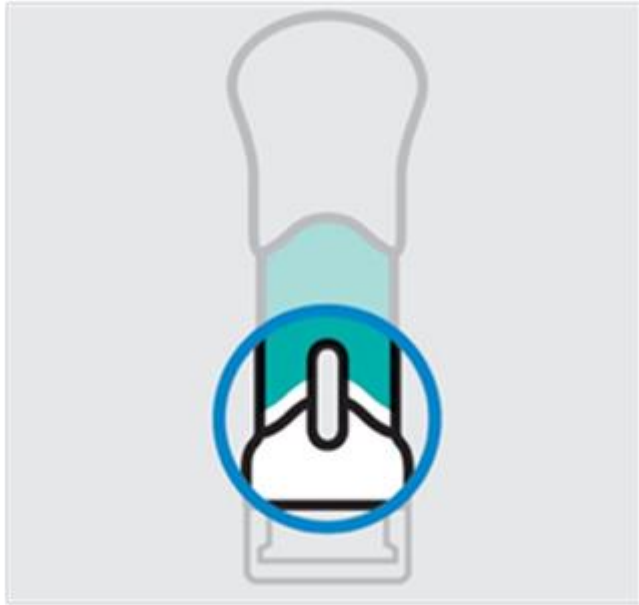
Wash hands

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

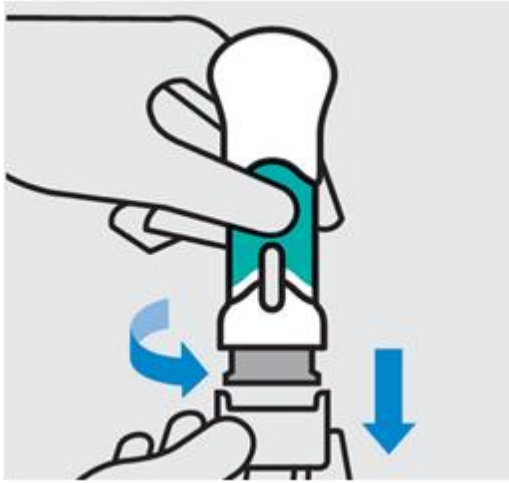
Take the pre-filled pen out of the carton.

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 discolored, or has large particles. If you are uncertain, call your doctor or pharmacist for a new pre-filled pen.

2. Inject TREMFYA® using the pre-filled pen



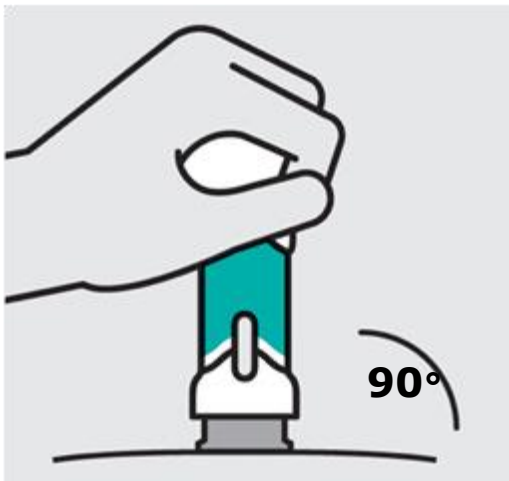
Twist and pull-off bottom cap

Keep hands away from the needle guard after the cap is removed.

Inject within 5 minutes of removing the cap.

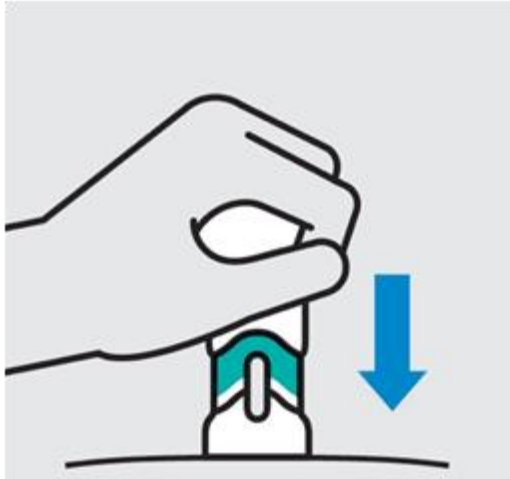
Do not put the cap back on, this could damage the needle.

Do not use the pre-filled pen if it is dropped after removing the cap. Call your doctor or pharmacist for a new pre-filled pen.



Place on skin

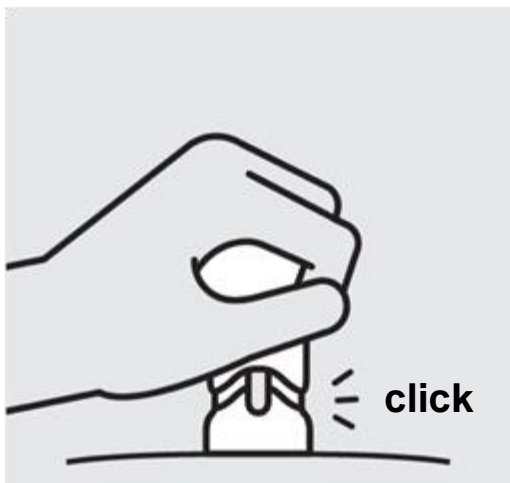
Position the pre-filled pen straight onto the skin (about 90 degrees relative to injection site).



Push handle straight down

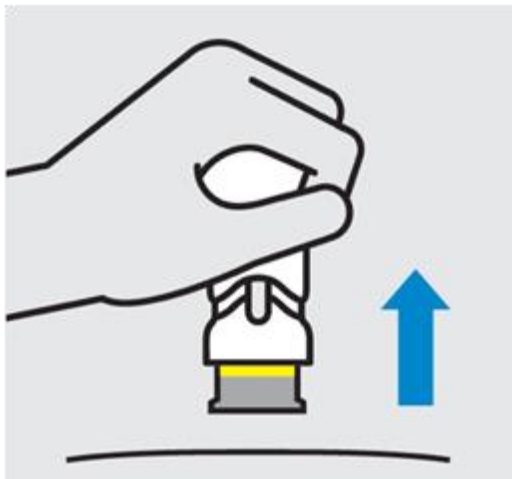
Medication injects as you push. Do this at a speed that is comfortable for you.

Do not lift the pre-filled pen 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 pre-filled pen away

Put your used pre-filled pen 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 Pen IFU Issued: 28 May 2018

BATCH RELEASER

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