

Package leaflet: Information for the user

Tremfya 200 mg concentrate for solution for infusion guselkumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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. Possible side effects
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 blocking the activity of a protein called IL-23, which is present at increased levels in people with Crohn's disease and ulcerative colitis.

Crohn's disease

Tremfya is used to treat adults with moderate to severe Crohn's disease, an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in Crohn's disease can benefit you by reducing the signs and symptoms of the disease such as diarrhoea, abdominal pain, and the inflammation of your intestinal lining. These effects can improve your ability to do normal daily activities and reduce fatigue.

Ulcerative colitis

Tremfya is used to treat moderate to severe ulcerative colitis in adults, an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in ulcerative colitis can benefit you by reducing the signs and symptoms of the disease including bloody stools, the need to rush to and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. These effects can improve your ability to do normal daily activities and reduce fatigue.

2. What you need to know before you use Tremfya

Do not use Tremfya

- if you are allergic to guselkumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Tremfya.
- if you have an active infection, including active tuberculosis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tremfya:

- if you are being treated for an infection;
- if you have an infection that does not go away or that keeps coming back;
- if you have tuberculosis or have been in close contact with someone with tuberculosis;
- if you think you have an infection or have symptoms of an infection (see below under ‘Look out for infections and allergic reactions’);
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with Tremfya.

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

As directed by your doctor, you may need blood tests to check if you have high levels of liver enzymes before you start taking Tremfya and when using it. Increases in liver enzymes may occur more frequently in patients receiving Tremfya every 4 weeks than in patients receiving Tremfya every 8 weeks (see “How to use Tremfya” in section 3).

Look out for infections and allergic reactions

Tremfya can potentially cause serious side effects, including allergic reactions and infections. You must look out for signs of these conditions while you are taking Tremfya.

Signs or symptoms of infections may include fever or flu like symptoms; muscle aches; cough; shortness of breath; burning when you urinate or urinating more often than usual; blood in your phlegm (mucus); weight loss; diarrhoea or stomach pain; warm, red, or painful skin or sores on your body which are different from your psoriasis.

Serious allergic reactions have occurred with Tremfya. Symptoms may include, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, lightheadedness or dizziness, or hives (see “Serious side effects” in section 4).

Stop using Tremfya and tell your doctor or seek medical help **immediately** if you notice any signs indicating a possible serious allergic reaction or an infection.

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 or pharmacist:

- if you are using, have recently used or might use any other medicines.
- if you recently had or are due to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Tremfya.

Pregnancy and breast-feeding

- Tremfya should not be used in pregnancy as the effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Tremfya and for at least 12 weeks

after the last Tremfya dose. Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

- 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 or use Tremfya.

Driving and using machines

Tremfya is unlikely to influence your ability to drive and use machines.

3. How to use Tremfya

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

How much Tremfya is given and for how long

Your doctor will decide for how long you need to use Tremfya.

Crohn's disease

Treatment start:

Treatment start can be given either by intravenous infusion or administered subcutaneously:

- Intravenous infusion: The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.
- Subcutaneous administration: The first dose of Tremfya is 400 mg and will be given under the skin (subcutaneous injection) at different locations of the body. After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy:

A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

Ulcerative Colitis

Treatment start:

- The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy:

A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

You may decide together with your doctor to give Tremfya yourself in which case you will get the appropriate training on how to inject Tremfya. Talk to your doctor or nurse if you have any questions about giving yourself an injection. It is important not to try to inject yourself until you have been trained by your doctor or nurse.

For detailed instructions on how to use Tremfya, carefully read the 'Instructions for use' leaflet before use, which is included in the carton.

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects

Tell your doctor or seek medical help immediately if you get any of the following side effects:

Possible serious allergic reaction (may affect up to 1 in 100 people) - the signs or symptoms may include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps
- lightheadedness, low blood pressure, or dizziness

Other side effects

The following side effects are all mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse immediately.

Very common (may affect more than 1 in 10 people)

- respiratory tract infections

Common (may affect up to 1 in 10 people)

- headache
- joint pain (arthralgia)
- diarrhoea
- increased level of liver enzymes in the blood
- skin rash

Uncommon (may affect up to 1 in 100 people)

- decreased number of a type of white blood cell called neutrophils
- herpes simplex infections
- fungal infection of the skin, for instance between the toes (e.g., athlete's foot)
- stomach flu (gastroenteritis)
- hives
- redness, irritation or pain at the injection site

Rare (may affect up to 1 in 1,000 people)

- allergic reaction

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tremfya

Tremfya 200 mg concentrate for solution for infusion is given in a hospital or clinic and patients should not need to store or handle it.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and on the outer carton after “EXP”. The expiry date refers to the last day of that month.

Keep the vial in the outer carton in order to protect from light.

Store in a refrigerator (2°C–8°C). Do not freeze.

Do not shake.

Do not use this medicine if you notice that the medicine is cloudy or discoloured, or contains large particles.

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.

6. Contents of the pack and other information

What Tremfya contains

- The active substance is guselkumab. Each vial contains 200 mg of guselkumab in 20 mL solution.
- The other ingredients are EDTA disodium dihydrate (E385), histidine, histidine monohydrochloride monohydrate, methionine, polysorbate 80 (E433), sucrose and water for injections.

What Tremfya looks like and contents of the pack

Tremfya is a clear, colourless to light yellow solution for infusion.

Each pack contains 1 vial.

Marketing Authorisation Holder

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Manufacturer

Cilag AG, Hochstrasse 201 , 8200 Schaffhausen, Switzerland

To contact us, please visit our website www.janssen.com/contact-us

This leaflet was last revised in 29-July-2024

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists



Tremfya 200 mg concentrate for solution for infusion

guselkumab

The following information is intended for healthcare professionals only.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Tremfya 200 mg/20 mL (10 mg/mL) Vial for Intravenous Infusion

Tremfya solution for intravenous infusion must be diluted, prepared and infused by a healthcare professional using aseptic technique. Tremfya does not contain preservatives. Each vial is for single use only.

Inspect Tremfya visually for particulate matter and discolouration prior to administration. Tremfya is a clear and colorless to light yellow solution that may contain small translucent particles. Do not use if the liquid contains large particles, is discoloured or cloudy.

Instructions for Dilution and Administration

Add Tremfya to a 250 mL intravenous infusion bag of 0.9% Sodium Chloride Injection as follows:

1. Withdraw and then discard 20 mL of the 0.9% Sodium Chloride Injection, from the 250 mL infusion bag which is equal to the volume of Tremfya to be added.
2. Withdraw 20 mL of Tremfya from the vial and add it to the 250 mL intravenous infusion bag of 0.9% Sodium Chloride Injection for a final concentration of 0.8 mg/mL. Gently mix the diluted solution. Discard the vial with any remaining solution.
3. Visually inspect the diluted solution for particulate matter and discolouration before infusion. Infuse the diluted solution over a period of at least one hour.
4. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein binding filter (pore size 0.2 micrometer).
5. Do not infuse Tremfya concomitantly in the same intravenous line with other medicinal products.
6. Dispose any unused medicinal product in accordance with local requirements.

Package leaflet: Information for the user

Tremfya 200 mg PushPen solution for injection in pre-filled pen guselkumab

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1. What Tremfya is and what it is used for

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Crohn's disease

Tremfya is used to treat adults with moderate to severe Crohn's disease, an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in Crohn's disease can benefit you by reducing the signs and symptoms of the disease such as diarrhoea, abdominal pain, and the inflammation of your intestinal lining. These effects can enable your normal daily activities and reduce fatigue.

Ulcerative colitis

Tremfya is used to treat adults with moderate to severe ulcerative colitis, an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in ulcerative colitis can benefit you by reducing the signs and symptoms of the disease including bloody stools, the need to rush to and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. These effects improve your ability to do normal daily activities and reduce fatigue.

2. What you need to know before you use Tremfya

Do not use Tremfya

- if you are allergic to guselkumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Tremfya.
- if you have an active infection, including active tuberculosis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tremfya:

- if you are being treated for an infection;
- if you have an infection that does not go away or that keeps coming back;
- if you have tuberculosis or have been in close contact with someone with tuberculosis;
- if you think you have an infection or have symptoms of an infection (see below under ‘Look out for infections and allergic reactions’);
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with Tremfya.

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

As directed by your doctor, you may need blood tests to check if you have high levels of liver enzymes before you start taking Tremfya and when using it. Increases in liver enzymes may occur more frequently in patients receiving Tremfya every 4 weeks than in patients receiving Tremfya every 8 weeks (see “How to use Tremfya” in section 3).

Look out for infections and allergic reactions

Tremfya can potentially cause serious side effects, including allergic reactions and infections. You must look out for signs of these conditions while you are taking Tremfya.

Signs or symptoms of infections may include fever or flu like symptoms; muscle aches; cough; shortness of breath; burning when you urinate or urinating more often than usual; blood in your phlegm (mucus); weight loss; diarrhoea or stomach pain; warm, red, or painful skin or sores on your body which are different from your psoriasis.

Serious allergic reactions have occurred with Tremfya. Symptoms may include, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, lightheadedness or dizziness, or hives (see “Serious side effects” in section 4).

Stop using Tremfya and tell your doctor or seek medical help **immediately** if you notice any signs indicating a possible serious allergic reaction or an infection.

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 or pharmacist:

- if you are using, have recently used or might use any other medicines.
- if you recently had or are due to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Tremfya.

Pregnancy and breast-feeding

- Tremfya should not be used in pregnancy as the effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Tremfya and for at least 12 weeks

after the last Tremfya dose. Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

- 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 or use Tremfya.

Driving and using machines

Tremfya is unlikely to influence your ability to drive and use machines.

3. How to use Tremfya

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

How much Tremfya is given and for how long

Your doctor will decide for how long you need to use Tremfya.

Crohn's disease

Treatment start:

Treatment start can be given either by intravenous infusion or administered subcutaneously:

- Intravenous infusion: The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.
- Subcutaneous administration: The first dose of Tremfya is 400 mg and will be given under the skin (subcutaneous injection) at different locations of the body. After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy:

A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

Ulcerative colitis

Treatment start:

- The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy:

A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

You may decide together with your doctor to give Tremfya yourself in which case you will get the appropriate training on how to inject Tremfya. Talk to your doctor or nurse if you have any questions about giving yourself an injection. It is important not to try to inject yourself until you have been trained by your doctor or nurse.

For detailed instructions on how to use Tremfya, carefully read the 'Instructions for use' leaflet before use, which is included in the carton.

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects

Tell your doctor or seek medical help immediately if you get any of the following side effects:

Possible serious allergic reaction (may affect up to 1 in 100 people) - the signs or symptoms may include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps
- lightheadedness, low blood pressure, or dizziness

Other side effects

The following side effects are all mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse immediately.

Very common (may affect more than 1 in 10 people)

- respiratory tract infections

Common (may affect up to 1 in 10 people)

- headache
- joint pain (arthralgia)
- diarrhoea
- increased level of liver enzymes in the blood
- skin rash

Uncommon (may affect up to 1 in 100 people)

- decreased number of a type of white blood cell called neutrophils
- herpes simplex infections
- fungal infection of the skin, for instance between the toes (e.g., athlete's foot)
- stomach flu (gastroenteritis)
- hives
- redness, irritation or pain at the injection site

Rare (may affect up to 1 in 1,000 people)

- allergic reaction

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tremfya

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pre-filled pen label and on the outer carton after “EXP”. The expiry date refers to the last day of that month.

Keep the pre-filled pen in the outer carton in order to protect from light.

Store in a refrigerator (2°C–8°C). Do not freeze.

Do not shake.

Do not use this medicine if you notice that the medicine is cloudy or discoloured, or contains large particles. 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.

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.

6. Contents of the pack and other information

What Tremfya contains

- The active substance is guselkumab. Each pre-filled pen contains 200 mg of guselkumab in 2 mL solution.
- The other ingredients are histidine, histidine monohydrochloride monohydrate, polysorbate 80 (E433), sucrose and water for injections.

What Tremfya looks like and contents of the pack

Tremfya is a clear, colourless to light yellow solution for injection (injection). It is available in packs containing one pre-filled pen and in multipacks comprising 2 cartons, each containing 1 pre-filled pen. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Manufacturer

Cilag AG, Hochstrasse 201 , 8200 Schaffhausen, Switzerland

To contact us, please visit our website www.janssen.com/contact-us

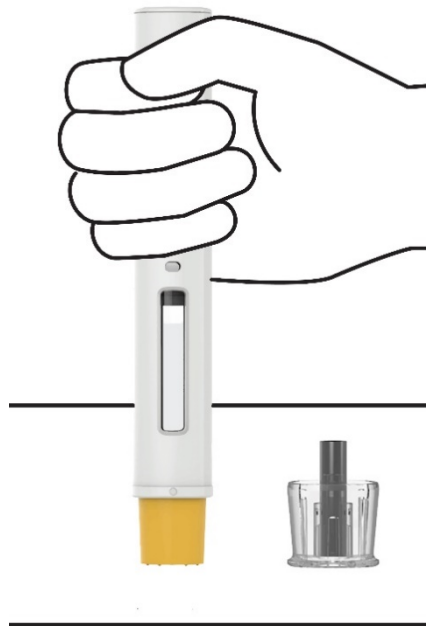
This leaflet was last revised in 29-July-2024

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

Instructions for use
Tremfya 200 mg PushPen
solution for injection in pre-filled pen



SINGLE-USE DEVICE

Important

Tremfya comes in a single-use pre-filled pen containing one 200 mg dose.

Your doctor will tell you if you will need to use 1 or 2 pre-filled pens.

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.

Each Tremfya pre-filled pen can only be used one time. Throw the used pre-filled pen away (see Step 4) after one dose, even if there is still medicine left in it. Do not reuse your pre-filled pen.

**Storage information**

Store in refrigerator at 2° to 8°C.

Do not freeze.

Do not shake your pre-filled pen.

Keep your pre-filled pen in the original carton to protect from light and physical damage.

Keep Tremfya and all medicines out of reach of children.

**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

Before use



After use

Plunger rod
fills the
viewing window



Viewing
Window

Yellow Needle
Guard

Thin Hidden
Needle



Cap
**Do not remove
until you are
ready to inject
(See Step 3)**

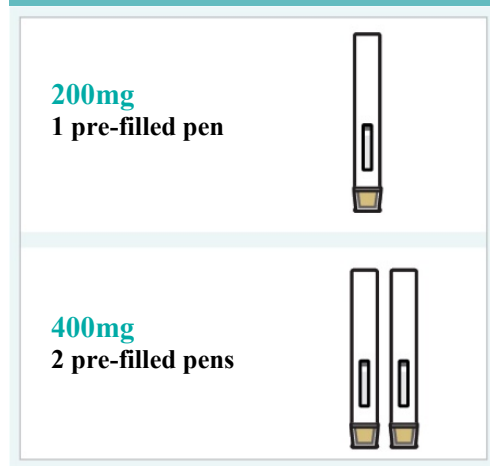
You will need:

- 1 or 2 pre-filled pens based on the dose prescribed by your doctor

Not provided in the carton:

- Alcohol swabs
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps container (See Step 4)

1. Get ready



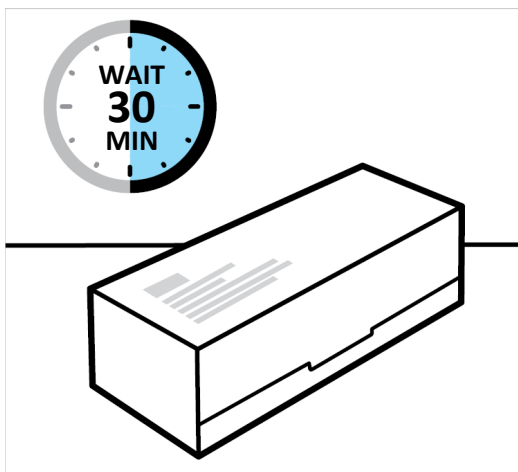
Check your prescribed dose to see if you will need to use 1 or 2 pre-filled pens and inspect carton(s)

Remove the carton(s) with the pre-filled pen from the refrigerator.

Check the expiry ('EXP') date on the carton.

Do not use the pre-filled pen if the expiry date has passed or if the seal on the carton is broken.

Call your doctor or pharmacist for a new pre-filled pen

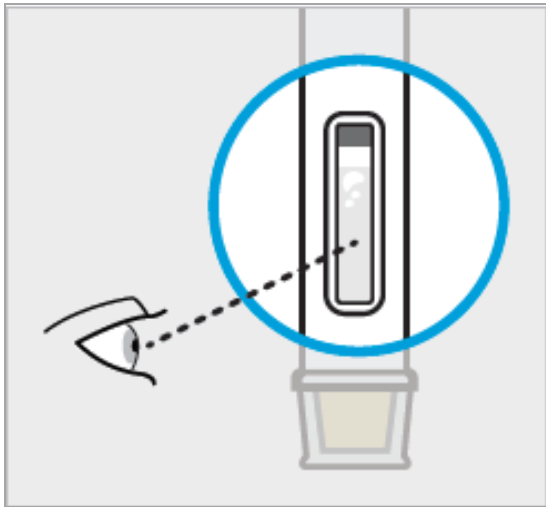


Allow Tremfya to come to room temperature

Let the carton sit on a flat surface at room temperature for approximately **30 minutes** before use.

Do not warm the pre-filled pen(s) any other way.

2. Prepare for your injection



Inspect liquid in window to see that it is clear to slightly yellow

Take the pre-filled pen 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 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.



Choose injection site

Select from the following areas for your injection:

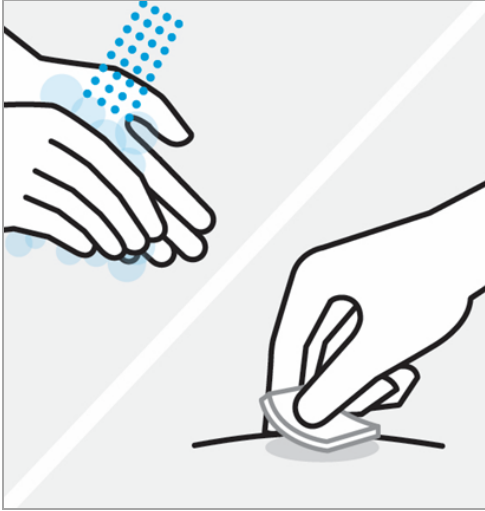
- Front of thighs
- Lower stomach area (lower abdomen)

Do not use the 5-centimetre area around your belly-button.

- Back of upper arms (if a caregiver is giving you the injection)

If you need to give 2 injections to complete your dose, choose different areas or leave at least 5-centimetres between injection sites.

Do not inject into skin that is tender, bruised, red, scaly, thick or hard. Avoid areas with scars or stretch marks.



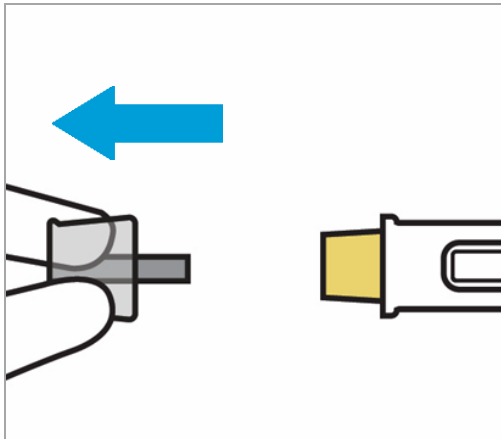
Wash hands and clean injection site

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.

3. Inject Tremfya using the pre-filled pen



Remove cap when you are ready to inject

Do Not Touch Yellow Needle Guard!

This may start the injection and you will not receive the dose.

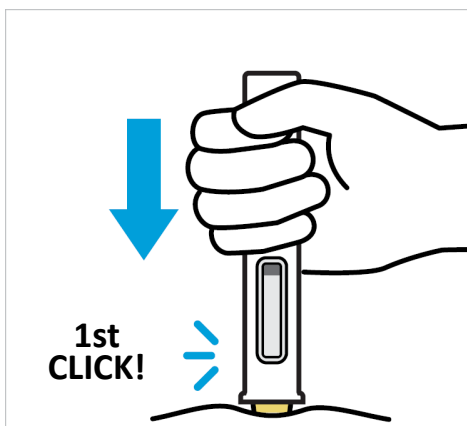
Pull the cap straight off. It is normal to see a few drops of liquid.

Inject Tremfya within 5 minutes of removing cap.

Do not put the cap back on as this may 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.



Position pre-filled pen straight onto the injection site then push and hold pre-filled pen

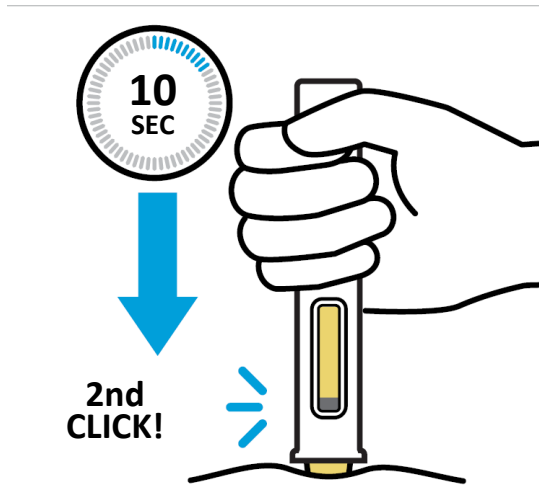
Do Not Lift The Pre-Filled Pen During Injection!

If you do, the yellow needle guard will lock and the full dose will not be delivered.

Position the pre-filled pen straight onto the injection site with the yellow needle guard against the skin and the viewing window facing you.

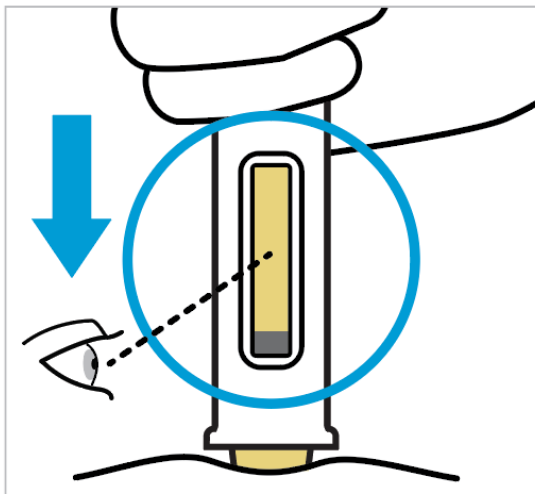
Press down on the pre-filled pen and keep holding it down against the skin.

You will hear the first click.



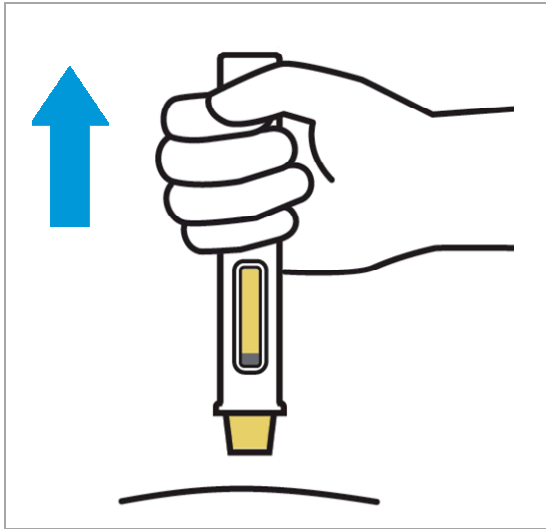
Keep holding the pre-filled pen firmly against the skin for about 10 seconds to hear a second click

You are almost done.



Keep holding firmly against the skin and confirm the injection is complete

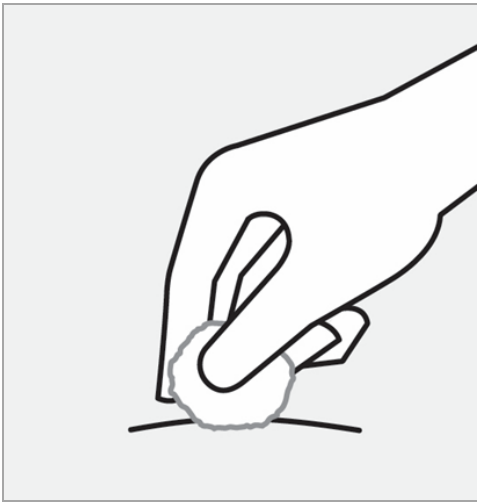
The injection is complete when the plunger rod stops moving and fills the viewing window.



Lift straight up

If your prescribed dose requires two injections, repeat Steps 2 to 4 with the second pre-filled pen.

4. After your injection



Check injection site

There may be a small amount of blood or liquid at the injection site. Gently hold pressure over the injection site with a cotton ball or gauze pad until any bleeding stops.

Do not rub the injection site. If needed, cover the injection site with a bandage.

Your injection is now complete!



Throw away the used pre-filled pen and cap

Put your used pre-filled pen and cap 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.

Do not throw away (dispose of) your pre-filled pen in your household waste.

Do not recycle your used sharps disposal container.

Package leaflet: Information for the user

Tremfya 100 mg solution for injection in pre-filled syringe guselkumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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. Possible side effects
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 blocking the activity of a protein called IL-23, which is present at increased levels in people with psoriasis ,psoriatic arthritis, Crohn's disease and ulcerative colitis.

Plaque psoriasis

Tremfya is used to treat adults with moderate to severe "plaque psoriasis", an inflammatory condition affecting the skin and nails.

Tremfya can improve the condition of the skin and appearance of nails and reduce symptoms, such as scaling, shedding, flaking, itching, pain and burning.

Psoriatic arthritis

Tremfya is used to treat a condition called "psoriatic arthritis", an inflammatory disease of the joints, often accompanied by plaque psoriasis. If you have psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, or in case of intolerance, you will be given Tremfya to reduce the signs and symptoms of the disease. Tremfya can be used alone or with another medicine named methotrexate.

Using Tremfya in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

Crohn's disease

Tremfya is used to treat adults with moderate to severe Crohn's disease, an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in Crohn's disease can benefit you by reducing the signs and symptoms of the disease such as diarrhoea, abdominal pain, and the inflammation of your intestinal lining. These effects can enable your normal daily activities and reduce fatigue.

Ulcerative colitis

Tremfya is used to treat adults with moderate to severe ulcerative colitis, an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or cannot tolerate these medicines, you may be given Tremfya.

Using Tremfya in ulcerative colitis can benefit you by reducing the signs and symptoms of the disease including bloody stools, the need to rush to and the number of times you go to the toilet, abdominal pain and the inflammation of your intestinal lining. These effects can improve your ability to do normal daily activities and reduce fatigue.

2. What you need to know before you use Tremfya

Do not use Tremfya

- if you are allergic to guselkumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Tremfya.
- if you have an active infection, including active tuberculosis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tremfya:

- if you are being treated for an infection;
- if you have an infection that does not go away or that keeps coming back;
- if you have tuberculosis or have been in close contact with someone with tuberculosis;
- if you think you have an infection or have symptoms of an infection (see below under 'Look out for infections and allergic reactions');
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with Tremfya.

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

As directed by your doctor, you may need blood tests to check if you have high levels of liver enzymes before you start taking Tremfya and when using it. Increases in liver enzymes may occur more frequently in patients receiving Tremfya every 4 weeks than in patients receiving Tremfya every 8 weeks (see "How to use Tremfya" in section 3).

Look out for infections and allergic reactions

Tremfya can potentially cause serious side effects, including allergic reactions and infections. You must look out for signs of these conditions while you are taking Tremfya.

Signs or symptoms of infections may include fever or flu like symptoms; muscle aches; cough; shortness of breath; burning when you urinate or urinating more often than usual; blood in your phlegm (mucus); weight loss; diarrhoea or stomach pain; warm, red, or painful skin or sores on your body which are different from your psoriasis.

Serious allergic reactions have occurred with Tremfya. Symptoms may include, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing, lightheadedness or dizziness, or hives (see “Serious side effects” in section 4).

Stop using Tremfya and tell your doctor or seek medical help **immediately** if you notice any signs indicating a possible serious allergic reaction or an infection.

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 or pharmacist:

- if you are using, have recently used or might use any other medicines.
- if you recently had or are due to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using Tremfya.

Pregnancy and breast-feeding

- Tremfya should not be used in pregnancy as the effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Tremfya and for at least 12 weeks after the last Tremfya dose. Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- 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 or use Tremfya.

Driving and using machines

Tremfya is unlikely to influence your ability to drive and use machines.

3. How to use Tremfya

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

How much Tremfya is given and for how long

Your doctor will decide for how long you need to use Tremfya.

Plaque psoriasis

- The dose is 100 mg (the content of 1 pre-filled syringe) given by injection under the skin (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.

Psoriatic arthritis

- The dose is 100 mg (the content of 1 pre-filled syringe) given by injection under the skin (subcutaneous injection). This may be given by your doctor or nurse.
- After the first dose, you will receive 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.

Crohn's disease

Treatment start:

Treatment start can be given either by intravenous infusion or administered subcutaneously:

- Intravenous infusion: The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.
- Subcutaneous administration: The first dose of Tremfya is 400 mg and will be given under the skin (subcutaneous injection) at different locations of the body. After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks.

Maintenance therapy:

A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

Ulcerative colitis

Treatment start:

- The first dose of Tremfya is 200 mg and will be given by your doctor or nurse by intravenous infusion (drip in a vein in your arm). After the first dose, you will receive a second dose 4 weeks later and then a third dose after an additional 4 weeks

Maintenance therapy:

A maintenance dose of Tremfya will be given by injection under the skin (subcutaneous injection) either with 100 mg or 200 mg. Your doctor will decide which maintenance dose you will receive:

- A dose of 100 mg will be given 8 weeks after the third treatment start dose, and then every 8 weeks.
- A dose of 200 mg will be given 4 weeks after the third treatment start dose and then every 4 weeks.

You may decide together with your doctor to give Tremfya yourself in which case you will get the appropriate training on how to inject Tremfya. Talk to your doctor or nurse if you have any questions about giving yourself an injection. It is important not to try to inject yourself until you have been trained by your doctor or nurse.

For detailed instructions on how to use Tremfya, carefully read the 'Instructions for use' leaflet before use, which is included in the carton.

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects

Tell your doctor or seek medical help immediately if you get any of the following side effects:

Possible serious allergic reaction (may affect up to 1 in 100 people) - the signs or symptoms may include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps
- lightheadedness, low blood pressure, or dizziness

Other side effects

The following side effects are all mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse immediately.

Very common (may affect more than 1 in 10 people):

- respiratory tract infections

Common (may affect up to 1 in 10 people):

- headache
- joint pain (arthralgia)
- diarrhoea
- increased level of liver enzymes in the blood
- skin rash

Uncommon (may affect up to 1 in 100 people):

- decreased number of a type of white blood cell called neutrophils
- herpes simplex infections
- fungal infection of the skin, for instance between the toes (e.g., athlete's foot)
- stomach flu (gastroenteritis)
- hives
- redness, irritation or pain at the injection site

Rare (may affect up to 1 in 1,000 people)

- allergic reaction

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tremfya

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the syringe label and on the outer carton after "EXP". The expiry date refers to the last day of that month.

Keep the pre-filled syringe in the outer carton in order to protect from light.

Store in a refrigerator (2°C–8°C). Do not freeze.

Do not shake.

Do not use this medicine if you notice that the medicine is cloudy or discoloured, or contains large particles. 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.

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.

6. Contents of the pack and other information

What Tremfya contains

- The active substance is guselkumab. Each pre-filled syringe contains 100 mg of guselkumab in 1 mL solution.
- The other ingredients are histidine, histidine monohydrochloride monohydrate, polysorbate 80 (E433), sucrose and water for injections.

What Tremfya looks like and contents of the pack

Tremfya is a clear, colourless to light yellow solution for injection (injection). It is available in packs containing one pre-filled syringe and in multipacks comprising 2 cartons, each containing 1 pre-filled syringe. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse-Belgium

Manufacturer

Cilag AG Hochstrasse 201, 8200 Schaffhausen-Switzerland

To contact us, go to www.janssen.com/contact-us

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

This leaflet was last revised in 06 August 2024.

Instructions for use

Tremfya

100 mg Pre-filled syringe



SINGLE-USE

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 these 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 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

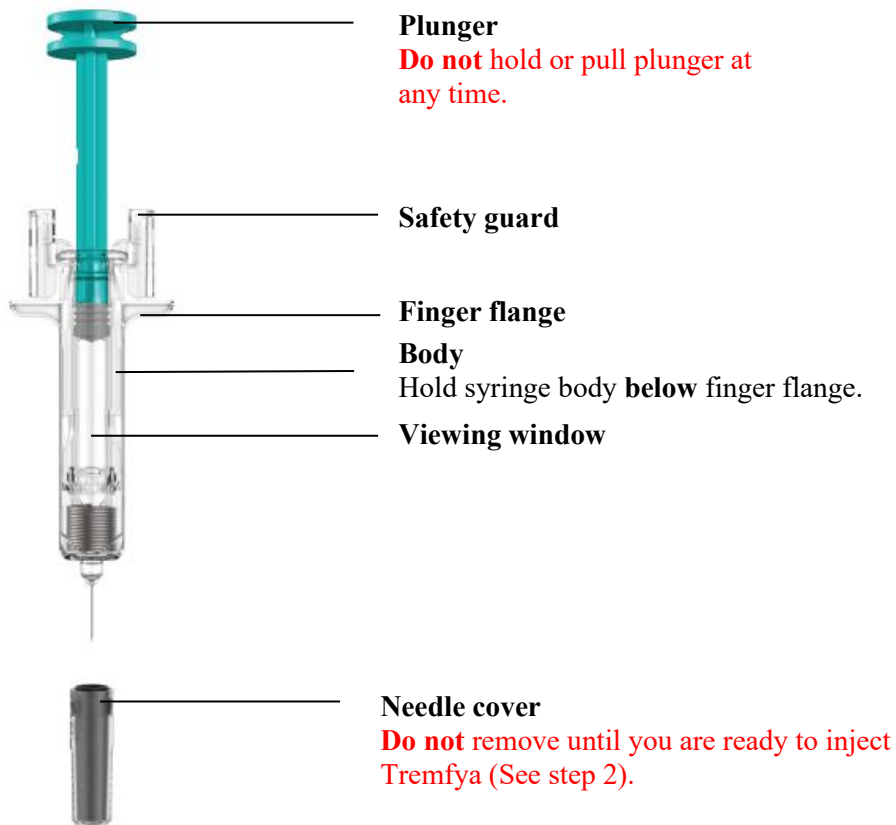
Store in refrigerator at 2° to 8°C. **Do not** freeze.

Keep Tremfya and all medicines out of reach of children.

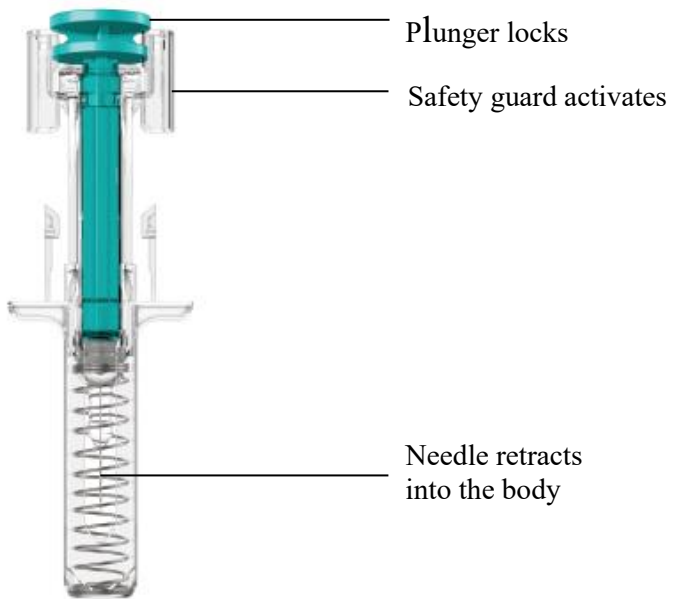
Do not shake the pre-filled syringe at any time.

Pre-filled syringe at-a-glance

Before injection



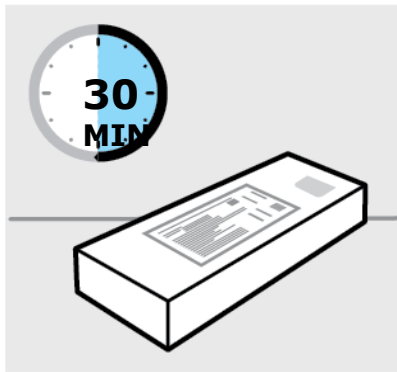
After injection



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 expiry date ('EXP') on the back panel of the carton.

Do not use if the expiry date has passed.

Do not inject if the perforations on the carton are broken.

Call your doctor or pharmacist for a refill.



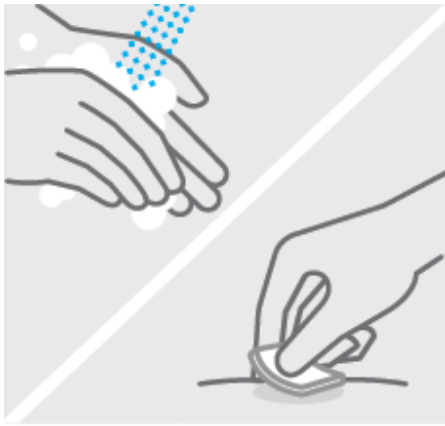
Choose injection site

Select from the following areas for your injection:

- **Front of thighs** (recommended)
- Lower abdomen
 - Do not** use the 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 or hard.

Do not inject into areas with scars or stretch marks.

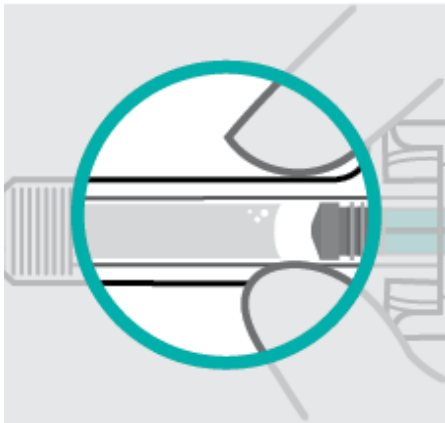


Clean injection site

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

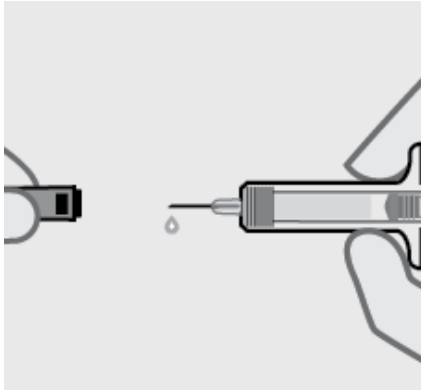
Take the pre-filled syringe out of the carton.

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 discoloured, 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.

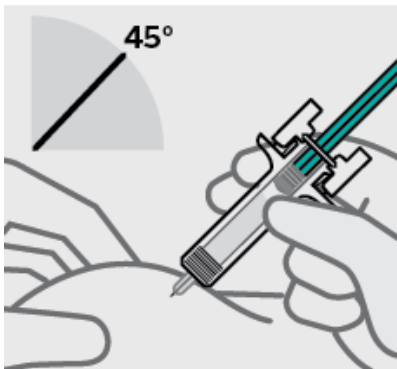
It is normal to see a drop of liquid.

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

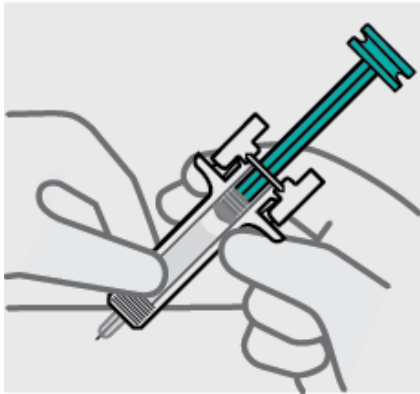
Place your thumb, index and middle fingers **directly under the finger flange**, as shown.

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.

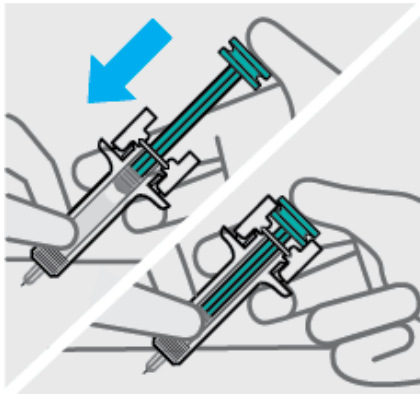
It is important to pinch enough skin to **inject under the skin** and not into the muscle.

Insert needle with a quick, dart-like motion.



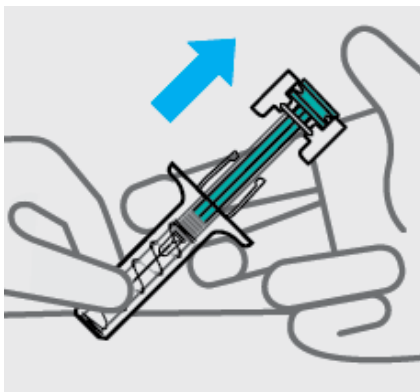
Release pinch and reposition hand

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.

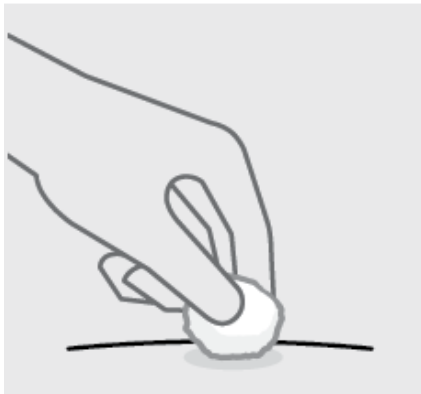
3. After your injection



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!



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.