

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Tremfya® pre-filled syringe/pre-filled pen, 100 mg

Each pre-filled syringe or pre-filled pen contains:

guselkumab 100 mg/1 ml

Inactive and allergenic ingredients in the preparation – see section 6 “Further information”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Tremfya is intended for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic treatment or phototherapy.

Therapeutic group: Interleukin inhibitors

Tremfya contains the active substance guselkumab which is a type of protein called a monoclonal antibody. The medicine works by blocking the activity of a protein called IL-23, which is present at high levels in people with psoriasis.

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

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:

- you are allergic to guselkumab or any of the additional ingredients contained in the medicine (as listed in section 6). If you think you may be allergic, consult the doctor before using the medicine.
- you have an active infection, including active tuberculosis.

☒ Special warnings regarding use of this medicine:

☒ Before beginning treatment with Tremfya, tell the doctor if:

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

If you are unsure if any of the sections above apply to you, consult the doctor, pharmacist or nurse before using the medicine.

☒ Look out for infections and allergic reactions

Tremfya may cause serious side effects, including allergic reactions and infections. Monitor for signs of these conditions while using Tremfya. Stop using Tremfya and immediately report to the doctor or seek medical help immediately if you notice any signs indicating possible serious allergic reactions or an infection.

Signs of infections may include fever or flu-like symptoms; muscle aches; cough; shortness of breath; stinging/burning sensation when passing urine or urinating more often than usual; bloody phlegm; weight loss; diarrhea or stomach pain; warm, red, or painful skin or sores on the body which are different from psoriasis.

Serious allergic reactions, which can include the following symptoms: swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing and hives, have been observed upon use of Tremfya (see “Serious side effects” in section 4 “Side effects”).

☒ Use in children and adolescents

Tremfya is not recommended for use in children and adolescents under the age of 18 because it has not been studied in these age groups.

☒ Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

In addition, if you recently received or are due to receive a vaccination, inform the doctor. Do not receive certain types of vaccinations (live vaccine) during treatment with Tremfya.

☒ Pregnancy and breastfeeding

• Do not use the medicine during pregnancy, as the effect of the medicine in pregnant women is not known. Women of childbearing age are advised to avoid becoming pregnant and to use contraception during the course of treatment with the medicine and for at least 12 weeks after taking the last dose of Tremfya.

Talk to the doctor if you are pregnant, think you may be pregnant or are planning a pregnancy.

• Talk to the doctor if you are breastfeeding or are planning to breastfeed. You and the doctor should decide if you should breastfeed or use Tremfya.

☒ Driving and operating machinery

It is unlikely that Tremfya will affect your ability to drive and operate machinery.

☒ Important information about some of the ingredients in this medicine

The medicine contains sucrose. Also see section 6 – “Further information”.

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

What dosage of the medicine is given and for how long?

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is:

- The dosage of the medicine is 100 mg (the contents of one pre-filled syringe or pre-filled pen), given as an injection under the skin. The treatment will be administered by a doctor or nurse.
- The second dose will be administered 4 weeks after administration of the first dose. Afterwards, a dose will be given every 8 weeks.

In the beginning, the doctor or nurse will inject the medicine. However, you may decide together with your doctor that you can inject the medicine on your own.

In this case, you will receive training on the correct manner of injecting Tremfya. Talk to the doctor or nurse if you have any questions about self-injecting the medicine. It is important not to inject the medicine yourself until you have received appropriate training by the doctor or nurse.

For detailed instructions for use, read the “Instructions for use” section below. Use this medicine at set intervals, as determined by the attending doctor. Adhere to the treatment regimen as recommended by the doctor.

If you accidentally take or receive a higher dosage or if you receive the medicine earlier than prescribed by the doctor:

Contact the doctor immediately.

If a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine:

Contact the doctor.

If you stop treatment with the medicine:

Do not stop treatment with the medicine without consulting the doctor. If you stop the treatment, the psoriasis symptoms may recur.

Do not exceed the recommended dose

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Tremfya may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Serious side effects (occur in 1-10 in 1,000 users)

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

Possible serious allergic reactions – the signs may include:

- difficulty breathing or swallowing.
- swelling in the area of the face, lips, tongue or throat.
- severe itching of the skin, with a red or raised rash.

Additional side effects

The following side effects are mild to moderate. If any of these side effects become severe, refer to a doctor immediately.

Very common side effects (occur in more than one in ten users)

- upper respiratory infections

Common side effects (occur in 1-10 in 100 users)

- headache
- joint pain (arthralgia)
- diarrhea
- intestinal inflammation (gastroenteritis)
- redness, irritation or pain at the injection site
- hives (urticaria)
- fungal infection of the skin, e.g., between the toes
- herpes simplex infection

Uncommon side effects (occur in 1-10 in 1,000 users)

- allergic reaction
- skin rash

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects

<https://sideeffects.health.gov.il>.

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

• Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.

• Keep refrigerated 2°C-8°C. Do not freeze.

• Protect from light.

• Do not shake.

• Do not use the medicine if you notice that the solution is cloudy, discolored or contains large particles.

Before use, take the carton out of the refrigerator. Leave the syringe or pre-filled pen in the carton until it reaches room temperature, by waiting 30 minutes.

• This medicine is intended for single use only.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Sucrose, L-Histidine, L-Histidine monohydrochloride monohydrate, Polysorbate 80, Water for injection

Sucrose content – 79 mg.

What the medicine looks like and the contents of the package:

Tremfya is a clear and colorless to light yellowish solution for injection. Each box contains one pre-filled syringe or pre-filled pen.

Registration Holder and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer: Cilag AG, Hochstrasse 201-8200, Schaffhausen, Switzerland.

Revised in July 2020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 160-54-35346

INSTRUCTIONS FOR USE:

Please find below separate instructions for use for the pre-filled syringe and then separate instructions for use for the pre-filled pen.

INSTRUCTIONS FOR USE OF TREMFYA PRE-FILLED SYRINGE:

If your doctor decides that you or your caregiver can inject Tremfya at home, you will have to receive training by a healthcare professional on the right way to use, prepare and inject Tremfya using the pre-filled syringe (see illustration 1) before you can inject the medicine by yourself.

Tremfya is supplied as a single-dose pre-filled syringe containing a dose of 100 mg. Each pre-filled syringe can be used only once. Discard the used syringe (see step 3) after using once, even if it is not completely empty. Do not reuse a Tremfya pre-filled syringe.

Do not try to self-inject Tremfya before receiving training by a healthcare professional about how to properly use the syringe product.

Read the instructions for use of the pre-filled syringe before each injection. The guidelines may be updated from time to time. This leaflet is not a substitute for consultation with the doctor regarding your medical condition or your treatment.

Tremfya pre-filled syringe is intended for injection under the skin, **and not** for injection into the muscle or vein. After injection, the needle will retract into the body of the syringe and lock into place.

Storage conditions

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

Keep out of reach of children.

Do not shake the Tremfya syringe.

Store in the original carton box to protect from light and mechanical damage.

Pre-filled syringe parts

Before use:

See illustration 2.

After use:

See illustration 3.

Supplies you will need for the injection:

1 pre-filled Tremfya syringe

Supplies not included in the Tremfya syringe pack:

1 alcohol swab/wipe

1 cotton ball or gauze pad

1 adhesive bandage

1 sharps container (see step 3).

1. PREPARING FOR INJECTION

Inspecting the carton (see illustration 4)

Take the Tremfya carton out of the refrigerator.

Leave the syringe in the box and place it on a flat surface at room temperature for **30 minutes** before use.

Do not warm the pre-filled syringe in any other way.

Check the expiration date ('EXP') on the back of the carton. **Do not** use the syringe if the expiry date has passed.

Do not use Tremfya if the box is not intact/is not closed well. Contact the doctor or pharmacist who dispensed the medicine to you.

Choosing the injection site (see illustration 5)

Select from the following areas for your injection:

- **Front of thigh** (recommended)
- Lower abdominal area, at a distance of at least 5 centimeters from the navel.
- Back of upper arms (only if a healthcare professional or caregiver is giving you the injection)

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

Cleaning the injection site (see illustration 6)

Wash your hands thoroughly with soap and hot water. Wipe the selected injection site with an alcohol swab and allow it to dry. **Do not** touch this area again and do not blow on it before the injection.

Inspecting the liquid in the syringe (see illustration 7)

Take the Tremfya syringe out of the box.

Check the syringe liquid in the viewing window. Make sure the liquid in the syringe is clear to slightly yellow. The liquid may contain tiny, partly clear or white particles. You may also see one or more air bubbles. This is normal.

Do not use if the liquid is discolored or cloudy, or contains large particles. If you are uncertain, contact the doctor or the pharmacist who dispensed this medicine to you.

2. INJECTING TREMFYA USING THE PRE-FILLED SYRINGE

Removing the needle cover (see illustration 8)

Hold the body of the syringe with one hand and pull the needle cover outward with your other hand. You may notice a drop of liquid at the tip of the needle – this is normal.

Inject Tremfya within 5 minutes of removing the needle cover.

Do not put the needle cover back on, as this may damage the needle.

Do not touch the needle and do not let the needle touch any surface.

Do not use the syringe if it has fallen. In such a situation, contact the doctor or the pharmacist who dispensed the medicine to you.

Positioning the fingers and inserting the needle (see illustration 9)

Place your thumb, index and middle fingers **directly under the finger flange**, as can be seen in the illustration.

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

With the other hand, gently pinch the skin at the injection site. Position the syringe at a 45-degree angle to the skin.

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

Insert the needle of the syringe with a quick motion.

Releasing the pinch and repositioning the hand (see illustration 10)

Use your free hand to grasp the body of the pre-filled syringe.

Pressing the plunger of the syringe (see illustration 11)

Place the thumb from the other hand on the plunger **and press the plunger all the way down until it stops**.

Releasing the thumb from the plunger (see illustration 12)

The safety guard will cover the needle and lock into place, while the needle is being removed from the skin.

3. AFTER THE INJECTION

Discarding the syringe (see illustration 13)

Discard the used Tremfya syringe into a sharps disposal container.

Do not discard the Tremfya syringe into a household wastebin.

Do not reuse the needles and syringes.

Check the injection site (see illustration 14)

You may notice a small amount of blood or liquid at the injection site. This is normal. Place a cotton ball or gauze pad on the injection site and press until the bleeding has fully stopped. **Do not** rub the area. If needed, place an adhesive bandage on the area.

For further information, refer to your doctor or pharmacist.

INSTRUCTIONS FOR USE OF TREMFYA PRE-FILLED PEN:

Single-use device

Important

If your doctor decides that you or your caregiver can inject Tremfya at home, you will have to receive training by a healthcare professional on the right way to use, prepare and inject Tremfya using the pre-filled pen, before you can inject the medicine by yourself.

Read the instructions for use of the pre-filled pen before each injection. The guidelines may be updated from time to time. This leaflet is not a substitute for consultation with the doctor regarding your medical condition or your treatment.

Carefully read the Tremfya Patient Leaflet as well before your injection. If you have any questions, refer to your doctor or nurse.

Storage conditions

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

Keep out of reach of children.

Do not shake the Tremfya pen at any time.

Pre-filled pen parts (see illustration 15)

Supplies you will need:

1 alcohol swab/wipe

1 cotton ball or gauze pad

1 adhesive bandage

1 sharps container (see step 3).

1. PREPARING FOR INJECTION

Inspecting the carton (see illustration 16)

Remove carton with the Tremfya pre-filled pen from the refrigerator.

Leave the pre-filled pen in the box and place it on a flat surface at room temperature for 30 minutes before use.

Do not warm the pre-filled pen in any other way.

Check the expiration date ('EXP') on the back of the carton. Do not use the pre-filled pen if the expiry date has passed.

Do not use Tremfya if the box is not intact/is not closed well. Contact the doctor or pharmacist who dispensed the medicine to you.

Choosing the injection site (see illustration 17)

Select from the following areas for your injection:

- Front of thigh (recommended)
- Lower abdominal area, at a distance of at least 5 centimeters from the navel.
- Back of upper arms (only if a healthcare professional or caregiver is giving you the injection).

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

Washing hands (see illustration 18)

Wash your hands thoroughly with soap and hot water.

Cleaning the injection site

Wipe the selected injection site with an alcohol swab and allow it to dry. Do not touch this area again and do not blow on it before the injection.

Inspecting the liquid in the pre-filled pen (see illustration 19)

Take the Tremfya pre-filled pen out of the box.

Check the liquid in the viewing window of the pre-filled pen. Make sure the liquid in the pre-filled pen is clear to slightly yellow. The liquid may contain tiny, partly clear or white particles. You may also see one or more air bubbles. This is normal.

Do not use if the liquid is discolored or cloudy, or contains large particles. If you are uncertain, contact the doctor or the pharmacist who dispensed the medicine to you.

2. INJECTING TREMFYA USING THE PRE-FILLED PEN

Twist and pull off cap (see illustration 20)

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

Inject Tremfya within 5 minutes of removing the cap.

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

Do not use the pre-filled pen if it has fallen after removing the cap. In such a situation, contact the doctor or the pharmacist who dispensed the medicine to you.

Placing the pre-filled pen on the skin (see illustration 21)

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

Push handle of pre-filled pen downwards (see illustration 22)

The medication is injected as you push. Press down 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

Completing the injection (see illustration 23)

Injection is complete when the handle is pushed all the way down, you hear a "click", and the green body is no longer visible.

Lift the pre-filled pen upwards (see illustration 24)

The yellow band indicates that the needle guard is locked.

3. AFTER THE INJECTION

Discarding the used pre-filled pen (see illustration 25)

Discard the used Tremfya pre-filled pen into a sharps disposal container immediately after use.

When the container is full, dispose of the bin according to the instructions you received from your doctor or nurse.

Check the injection site (see illustration 26)

You may notice a small amount of blood or liquid at the injection site. Place a cotton ball or gauze pad on the injection site and press until the bleeding has fully stopped. Do not rub the area. If needed, place an adhesive bandage on the area.

The injection is now complete!

For further information, refer to your doctor or pharmacist.