

TREMFYA® Abbreviated Prescribing Information:

Therapeutic Indication:

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 and psoriatic arthritis.

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 psoriasis. If you have psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, 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.

Dose :

Plaque psoriasis

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

At the start, your doctor or nurse will inject Tremfya. However, 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.

If you use more Tremfya than you should

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

If you forget to use Tremfya

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

If you stop using Tremfya

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

Contraindications:

Do not use Tremfya

- if you are allergic to guselkumab or any of the other ingredients of this medicine. 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.

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. 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.

Signs 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, which can include the following symptoms, swollen face, lips, mouth, tongue or throat, difficulty swallowing or breathing and hives, have occurred with Tremfya.

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.

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.

Possible side effects :

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 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

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.

- respiratory tract infections
- Some side effects are common (may affect up to 1 in 10 people):

- headache
- joint pain (arthralgia)
- diarrhoea
- redness, irritation or at the injection site
- increased level of liver enzymes in the blood

Some side effects are uncommon (may affect up to 1 in 100 people):

- allergic reaction
- skin rash
- 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

Always read the full prescribing information.

Healthcare professionals are asked to report any suspected adverse reactions to Egyptian pharmacovigilance center (EPVC).

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