Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Enjaymo

Solution for infusion

Active ingredient: Each ml contains 50 mg of sutimlimab.
Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

In addition to the leaflet, Enjaymo has a patient safety information guide. This guide contains important safety information that you need to know and that you should follow before starting and during treatment with Enjaymo. Carefully read the patient safety information guide and the patient information leaflet before using this medicine. Keep the guide in case you need to read it again.

1. What is this medicine intended for?

Enjaymo is used to treat haemolysis in adults with cold agglutinin disease (CAD).

Therapeutic group: monoclonal antibodies.
In the rare blood disorder cold agglutinin disease (CAD), certain antibodies of the immune defence system bind to red blood cells. This causes breakdown of the red blood cells (haemolysis) through activation of classical complement pathway (part of the immune defence system). Enjaymo blocks the activation of this part of the immune defence system.

2. Before using the medicine

Do not use this medicine if:

You are sensitive (allergic) to sutimlimab or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine
Talk to your doctor before you are given Enjaymo.

Infections

Inform your doctor if you have any infection, including an ongoing infection such as HIV, hepatitis B or hepatitis C or if you have a decreased ability to fight infections.

Vaccinations

Check with your doctor that you are appropriately vaccinated, and also have received meningococcal and streptococcal vaccines.

It is recommended that you are vaccinated at least 2 weeks before beginning Enjaymo. You need to be aware that vaccination may not always prevent these types of infection. Immediately contact your doctor if any signs of infection appear, see section 4 'Side effects'.

Allergic reactions

Seek medical help immediately if you notice any signs of an allergic reaction while or after you are given this medicine. For symptoms, see section 4 'Side effects'.

Infusion-related reactions

You may experience infusion-related reactions during the infusion or immediately after the infusion. Inform the medical staff immediately if you experience symptoms associated with Enjaymo infusion. For symptoms, see section 4 'Side effects'.

Systemic lupus erythematosus (SLE)

Inform your doctor if you have an autoimmune disease such as systemic lupus erythematosus (SLE), also known as lupus. Seek medical attention if you develop any symptoms of SLE such as joint pain or swelling, rash on the cheeks and nose or unexplained fever.

Children and adolescents
Enjaymo should not be used in children and adolescents under 18 years of age. Enjaymo is not indicated for treatment of children and adolescents under 18 years of age as CAD generally does not occur in this age group.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before being given this medicine. Information about administration of Enjaymo during pregnancy and its effect on your unborn baby is limited. It is not known if Enjaymo will affect your unborn baby. You should therefore refrain from using Enjaymo during pregnancy.

If you are pregnant, you should only receive treatment with Enjaymo if your doctor has clearly recommended it.

Breast-feeding

It is not known whether Enjaymo passes into breast milk. If you are breast-feeding or planning to breast-feed, talk to your doctor before using this medicine. You and your doctor will decide whether you should stop breast-feeding or stop/refrain from treatment with Enjaymo while considering the benefit of breast-feeding for the child and the benefit of treatment for the woman.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.

Important information about some of this medicine's ingredients
Enjaymo contains sodium.
This medicine contains 3.5 mg per ml or 77 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.85% of the recommended maximum daily consumption of sodium for an adult.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.
Adhere to the treatment as recommended by your doctor. **Do not exceed the recommended dose.**

Enjaymo will be given to you by a healthcare professional. It is given as an infusion (drip) into a vein (intravenously). The dose you will be given will depend on your body weight.

The infusion takes usually 1 to 2 hours. After each infusion you will be monitored for allergic reactions: after the first infusion you will be monitored for at least 2 hours. After the subsequent infusions you will be monitored for at least 1 hour.

You will usually receive:
- an initial dose of Enjaymo
- a dose of Enjaymo one week later
- thereafter you will start to receive Enjaymo every 2 weeks

Home infusion

- You will receive Enjaymo for at least three months at a healthcare facility.
- After this, your doctor may consider that you can have home infusion of Enjaymo.
- Home infusion will be performed by a healthcare professional.

If you have accidentally been given a higher dose of Enjaymo
This medicine will be given by a healthcare professional. If you think that you have been accidentally given too much Enjaymo, please contact your doctor for advice.

If you forget to use Enjaymo
If you miss an appointment to receive Enjaymo, contact your doctor right away to reschedule your infusion.

If you stop using Enjaymo
The effects of Enjaymo will be reduced after end of the treatment. If you stop receiving Enjaymo, your doctor should check for return of signs and symptoms of CAD. The symptoms are caused by breakdown of your red blood cells and may include tiredness, shortness of breath, rapid heart rate or dark urine.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Enjaymo may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.
Immediately tell the medical staff giving you Enjaymo if you notice any signs of an allergic reaction while or shortly after you are given this medicine. 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
- feeling faint.

If any of these symptoms occur during infusion, the infusion should be stopped immediately.

Immediately tell the medical staff giving you Enjaymo if you notice any signs of a reaction related to the infusion while you are given this medicine. Common (may affect up to 1 in 10 people).
The signs may include:
- nausea
- feeling flushed
- headache
- shortness of breath
- rapid heart rate.

Tell your doctor as soon as possible if you experience symptoms or signs of an infection such as:
- fever with or without rash, chills, flu-like symptoms, cough/difficulty breathing, headache with nausea, vomiting, stiff neck, stiff back, confusion, eye sensitivity to light, pain during urination or urinating more often.
- Infections of the urinary tract, upper respiratory tract, stomach and intestine, common cold, runny nose are very common (may affect more than 1 in 10 people).
- Infections of the lower respiratory tract, urinary tract, herpes infection are common (may affect up to 1 in 10 people).

Tell your doctor or nurse if you get any of the following other side effects:

Very common side effects (may appear in more than 1 in 10 people):
- headache
- high blood pressure
- poor circulation with skin discolouration in hands and feet in response to cold and stress (Raynaud's phenomenon, acrocyanosis)
- abdominal pain
- nausea

Common side effects (may appear in up to 1 in 10 people):
- Infusion-related reactions
- Fever
- Feeling cold
- Dizziness
- Aura
- Low blood pressure
- Diarrhoea
- Stomach discomfort
- Mouth ulcer (aphthous ulcer)
- Chest discomfort
- Itching

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions
Store in a refrigerator (2°C-8°C). Do not freeze. Store in the original package to protect from light.
Do not throw away medicines via wastewater or household waste. Ask your doctor, pharmacist or nurse how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Sodium chloride, sodium phosphate monobasic, monohydrate, sodium phosphate dibasic, heptahydrate, polysorbate 80, water for injections

This medicine contains sodium (see section 2 'Enjaymo contains sodium').

What the medicine looks like and contents of the pack:
Enjaymo is an opalescent, colourless to slightly yellow solution for infusion, essentially free from particles.
Each pack contains one vial.

Registration holder's, importer's name and address: Sanofi Israel Ltd., Greenwork Park, P.O. box 47, Yakum.

Revised in June 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 174-82-37417.

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המידע הבא מיועד לאנשי הצוות הרפואי בלבד:
المعلومات التالية مخصصة للطاقم الطبي فقط:
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.

Preparation

Enjaymo is provided as a solution in a single-dose vial and should be prepared by a healthcare professional using aseptic technique.

1. Remove Enjaymo from the refrigerator. To minimize foaming, do not shake.
2. Inspect vials visually for particulate matter and discolouration prior to administration. The solution is an opalescent and colourless to slightly yellow liquid. Do not administer if discoloured or if other foreign particulate matter is present.
3. Withdraw the calculated volume from the appropriate number of vials based on the recommended dose (see Table 1 for the infusion reference) and add to an empty infusion bag. Discard any unused portion remaining in the vial.
4. The prepared solution should be administered immediately.

Administration

1. Prior to administration, allow the infusion solution to adjust to room temperature (18°C-25°C). Refer to Table 1 for infusion rate. The infusion should be administered over 1-2 hours depending on the patient's body weight. Administer the infusion only through a 0.22-micron filter with a polyethersulfone (PES) membrane. Infusion warmers may be used, do not exceed a temperature of 40°C.
2. The infusion catheter and tubing should be primed with the dosing solution immediately before infusion and flushed immediately following completion of the infusion with enough quantity (approximately 20 mL) of sodium chloride 9 mg/mL (0.9%) solution for injection.
3. No incompatibilities have been observed between Enjaymo infusion solution and infusion bags made of Di-(2-ethylhexyl) phthalate (DEHP) plasticized polyvinyl chloride (PVC), Ethyl Vinyl Acetate (EVA) and polyolefin (PO); administration sets made of DEHP-plasticized PVC, DEHP-free polypropylene (PP) and polyethylene (PE); and vial adapters made of polycarbonate (PC) and acrylonitrile-butadiene-styrene (ABS).

Table 1 - Infusion reference table

Body weight range	Dose (mg)	Number of vials needed	Volume (mL)	Maximum infusion rate
Greater than or equal to 39 kg to less than 75 kg	6500	6	130	130 mL/hour
75 kg or greater	7500	7	150	150 mL/hour

Storage conditions

Unopened vial
- Store in a refrigerator (2°C-8°C). Do not freeze.
- Store in the original carton in order to protect from light.

After opening
- Chemical and physical in-use stability has been demonstrated for 16 hours at 18°C to 25°C or for 36 hours at 2°C to 8°C. From a microbiological point of view, the product should be used immediately.
- If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be for longer than 24 hours at 2°C to 8°C or 8 hours at room temperature, unless vial opening and pooling into the infusion bag has taken place in controlled and validated aseptic conditions.

Home infusion

Home infusions should be performed by a healthcare professional.
The decision to consider home infusion should be based on individual clinical characteristics of the patient and individual needs of the patient. Transitioning the infusion from a clinical facility to home administration includes ensuring that adequate infrastructure and resourcing is in place and consistent with treating physician orders. Infusion of Enjaymo at home may be considered for patients who have tolerated their infusion well in a clinical facility and have not had infusion related reactions. A patient's underlying co-morbidities and ability to adhere to the home infusion requirements need to be considered when evaluating the patient for eligibility to receive home infusion. In addition, the following criteria should be considered:

- The patient must have no ongoing concurrent condition that, in the opinion of the physician, may place the patient at greater risk when receiving an infusion in the home setting rather than in the clinic setting. A comprehensive evaluation should be completed before the initiation of home infusion to ensure that the patient is medically stable.
- The patient must have successfully received Enjaymo infusion in a clinical setting (hospital or outpatient) for at least three months under the supervision of a physician or care provider experienced in the management of patients with CAD.
- The patient must be willing and able to comply with home infusion procedures and recommendations of the treating physician or care provider.
- The healthcare professional administering the infusion at home should be available at all times during the home infusion and for at least 1 hour after infusion.

If the patient experiences adverse reactions during the home infusion, the infusion process should be stopped immediately, appropriate medical treatment should be initiated and the treating physician should be notified. In such cases, the treating physician should decide if subsequent infusions should occur and if so, whether the infusions should be administered in a hospital or supervised outpatient care setting.