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

This medicine is dispensed with a doctor's prescription only

SAPHNELO®

Concentrate for solution for intravenous infusion

Each vial (2 ml) contains:
Anifrolumab 300 mg (300 mg/2mL)

Each 1 ml contains: anifrolumab 150 mg (150 mg/mL)

For inactive ingredients in the medicine - please 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 any further questions, ask the 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 ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

SAPHNELO is indicated for the treatment of adult patients with moderate to severe systemic lupus
erythematosus (SLE), who are receiving standard therapy.

Limitations of Use

The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of SAPHNELO is not recommended in these situations.

Therapeutic group

Selective immunosuppressants

Lupus is a disease of the immune system (the body system that fights infection). When given together with other medicines for lupus, SAPHNELO may help to reduce your lupus disease activity more than other lupus medicines alone.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see section 6).

Special warnings regarding the use of this medicine

Before treatment with SAPHNELO, tell the doctor if:

- You think you have an infection or have infections that keep coming back. You should not receive SAPHNELO if you have an infection unless your doctor tells you to (See section "SIDE EFFECTS")
- You are scheduled to receive a vaccination or if you think you may need a vaccination. You should not receive live vaccines during treatment with SAPHNELO.
- You have or have had any type of cancer.
- You are receiving other biologic medicines or monoclonal antibodies.

Children and adolescents:

There is no information regarding the safety and efficacy of the use of this medicine in children and adolescents under 18 years of age.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. SAPHNELO may affect the way other medicines work, and other medicines may affect how SAPHNELO works.

Pregnancy and breastfeeding:

Pregnancy

Tell the doctor if you are pregnant, think you may be pregnant or planning to become pregnant during treatment with SAPHNELO.

There is insufficient information on the use of SAPHNELO in pregnant women, whether SAPHNELO causes birth defects, miscarriages or unwanted effects on the mother or fetus.

Breastfeeding

Tell the doctor if you are breastfeeding or plan to breastfeed.
No data are available regarding the presence of SAPHNELO in human milk, the effects on the breastfed child, or the effects on milk production.

Driving and operating machinery

It is unlikely that this medicine will affect your ability to drive and use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.
The dosage and manner of treatment will be determined by the doctor only.
The recommended dosage is usually: 300 mg.
SAPHNELO will be given to you by the nurse or the doctor through intravenous infusion over 30 minutes, 1 time every 4 weeks.
Do not co-administer other medicines through the same infusion line.
Preparation instructions in English, intended for medical staff, can be found in the "Instructions for preparation and Administration" section on the other side of this leaflet.

Do not exceed the recommended dose.

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

If you forgot to take the medicine

If you miss an infusion appointment, contact the doctor as soon as possible to reschedule your appointment
Adhere to the treatment as recommended by your doctor.

If you stop taking the medicine

Do not change the dosage or stop treatment without consulting the attending doctor.

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

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

4. SIDE EFFECTS

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

SAPHNELO may cause serious side effects, including:

- **Serious Infections:** SAPHNELO can lower the ability of your immune system to fight infections. You may be at a higher risk of developing respiratory infections and shingles (herpes zoster) during treatment with SAPHNELO. Infections could be serious, leading to hospitalization or death. **Contact your doctor right away if you have any of the following symptoms of an infection:**
  - fever, sweating, or chills
  - muscle aches
  - cough
  - shortness of breath
  - burning when urinating
  - urinating more often
  - diarrhea or stomach pain
  - warm, red, or painful skin or sores on your body.
- **Allergic (hypersensitivity) reactions,** including anaphylaxis. Serious allergic reactions can happen during or after you get your SAPHNELO infusion. **Contact your doctor or get emergency help right away if you have any of the following symptoms of a serious allergic reaction:**
  - swelling of your face, mouth or tongue
  - breathing problems
  - fainting or dizziness

- feeling lightheaded (low blood pressure)
- **Cancer:** SAPHNELO may reduce the activity of the immune system. Medicines that affect the immune system may increase your risk of certain cancers.

Common side effects (side effects occurring in 1-10 of 100 users):

- upper respiratory infections
- infusion reactions
- cough
- bronchitis
- shingles (herpes zoster)

If a side effect appears, if any of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of 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, or by entering the link: https://sideeffects.health.gov.il

5. HOW TO STORE ENHERTU?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants 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.
- Store in a refrigerator at 2°C to 8°C in the original carton to protect from light. Do not freeze. Do not shake.
- Administer the solution immediately after preparation.
- If the solution is not administered immediately after preparation, store the diluted solution at room temperature (15°C to 25°C) for up to 4 hours, or refrigerated (2°C to 8°C) for up to 24 hours. Do not freeze. If refrigerated, allow the diluted solution to reach room temperature prior to administration.
- Each vial is for single use only.
- Any unused solution should be discarded.

6. FURTHER INFORMATION

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

α,α-Trehalose dihydrate, L-lysine hydrochloride, L-histidine hydrochloride monohydrate, L-histidine, polysorbate 80 and Water for Injection.

What the medicine looks like and the content of the package?

SAPHNELO is a sterile, preservative-free, clear to opalescent solution. The solution is colorless to slightly yellow, and comes in a single-dose vial.

Manufacturer: AstraZeneca AB, Södertälje, Sweden.

License Holder and importer: AstraZeneca (Israel) Ltd., 1 Atirei Yeda St., Kfar Saba 4464301.

Approved in April 2022 according to the MoH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

169-50-37020-00