Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is to be supplied by physician's prescription only

Ospolot
Film-coated tablets

Active ingredient:
Each tablet contains:
sulthiame 200 mg

Each tablet contains 50 mg lactose monohydrate.

Inactive ingredients and allergens in the medicine: see section "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, contact the physician or pharmacist.

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

1. What is this medicine intended for?

Ospolot is indicated for the treatment of epilepsy in adults and in treatment of the so called focal benign epilepsy of children, when other medication was not adequate.

Therapeutic group: Carbonic anhydrase inhibitors.

2. Before using this medicine

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredient sulthiame, or to medicines from the sulpha group, and/or to any of the other ingredients of this medicine (please see section 6).
- You suffer from hyperthyroidism.
- You suffer or have previously suffered from congenital or acquired acute porphyria, which affects the production of hemoglobin in your body.
- You suffer from high blood pressure.

Special warnings regarding the use of this medicine
Prior to commencing treatment with Ospolot, **tell the physician if:**
- you suffer or have previously suffered from impaired renal function
- you suffer or have previously suffered from psychiatric disorders

Contact the attending physician immediately if any one or more of the following appear:
- Fever, sore throat, allergic skin reaction accompanied by lymph node swelling and/or occurrence of flu-like symptoms during treatment with **Ospolot.** In such cases, ensure performing a blood count.
- Changes in blood test results such as a decrease in white blood cell count or platelet count (leucopenia or thrombocytopenia), that occur with other symptoms such as fever and sore throat. The physician may decide to stop treatment with **Ospolot** immediately.
- In case of severe allergic reaction, **Ospolot** treatment must be discontinued immediately.

Tests and follow up:
- It is advisable to perform blood tests, liver function and renal function tests before starting treatment with **Ospolot**; subsequently, it is advisable to perform blood tests once a week during the first month of treatment with **Ospolot**, and once a month after that. After six months of treatment with **Ospolot**, it is advisable to perform these tests at least two to four times a year.
- There are reports of some patients who were treated with anti-epileptic medicines such as **Ospolot**, who expressed a wish to harm themselves, or experienced suicidal thoughts. If you have had such thoughts at any time during treatment with **Ospolot**, contact the physician immediately.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, inform the physician or pharmacist. In particular, if you are taking:

Medicines for treating epilepsy:

- Phenytoin - Levels of phenytoin in your blood may rise significantly. Combination therapy with **Ospolot** and this medicine requires close medical follow up. You must regularly perform blood tests to monitor phenytoin levels in your blood, particularly if you have impaired renal function.
- Lamotrigine - In some cases, the levels of lamotrigine in your blood may rise as a result of combination therapy with **Ospolot** and this medicine. Therefore, at the beginning of treatment, it is advisable to perform blood tests to monitor lamotrigine levels in your blood.
- Primidone - Combination therapy with **Ospolot** and primidone may cause severe side effects, especially in children, including dizziness, unstable gait, drowsiness, and psychotic reactions.
- Carbamazepine - Combination therapy with **Ospolot** and carbamazepine may cause a decrease in **Ospolot** levels in your blood.

Combination therapy with **Ospolot** and other carbonic anhydrase inhibitors, such as topiramate (for treatment of epilepsy and migraine) or acetazolamide (for treatment of intraocular pressure) may increase the risk of side effects occurrence.

Using Ospolot and food

Ospolot can be taken with or without food. There are no restrictions on the types of food and drink you can have*.*

Using Ospolot and alcohol consumption

Do not drink alcoholic beverages during treatment with **Ospolot.**

Drinking alcohol during treatment with **Ospolot** may have an unexpected influence on the effect of **Ospolot.** In addition, it may cause vasodilatation, pulsating headache, shortness of breath, nausea, vomiting, rapid pulse, decrease in blood pressure, blurred vision, confusion, body shock reaction, cardiac arrhythmia, loss of consciousness, and seizures.These seizures may vary in their frequency and intensity.

Pregnancy, breastfeeding and fertility:

Do not take **Ospolot** if you are pregnant or breastfeeding.

Pregnancy:

If you think you are pregnant or planning to become pregnant, inform the physician so that he may consider whether to start treatment with **Ospolot.**

Use of **Ospolot** during pregnancy is associated with an increased risk to the fetus. You should therefore refrain from using the medicine during pregnancy unless the attending physician has expressly prescribed it for you. If you are a woman of childbearing age and are taking **Ospolot,** you must use an effective method of contraception.

Do not stop treatment with **Ospolot** without discussing this with the attending physician. Sudden discontinuation of treatment or reducing the dose in an uncontrolled manner may lead to recurrence of epileptic seizures, which may harm you and/or your unborn child.

Breastfeeding:

It is not known whether the active ingredient of **Ospolot** passes into breast milk, therefore do not take **Ospolot** if you are breastfeeding.

Driving and using machines:

Use of this medicine may cause changes in reactions, therefore using **Ospolot** requires caution when driving a car, operating dangerous machines and performing any other activity that requires alertness. This warning applies especially when combining **Ospolot** with alcohol. Children must be warned against riding bicycles, playing near roads, etc.

Important information about some of the medicine's ingredients:

Ospolot contains lactose. If you are intolerant to certain sugars, consult the physician before starting treatment with **Ospolot.**

3. How should you use the medicine?

Always use **Ospolot** according to the physician's instructions. You should check with the physician or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.
The dosage and manner of treatment will be determined only by the physician. The recommended dose is usually:

- The accepted maintenance dosage is 5-10 mg per kilogram body weight per day. This dose must be reached gradually over the first week of **Ospolot** treatment.
- Switching to **Ospolot** from another medicine or another combination must be done gradually, not all at once.
- The tablets may be split on the score line.
- Swallow the tablets with at least one glass of water.
- Your daily dosage can be divided into three doses taken during the day.
- Do not take **Ospolot** while lying down.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, go immediately to a hospital emergency room or see a physician and bring the medicine package with you. If this occurs, the side effects listed in this leaflet may be intensified.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the physician.

Adhere to the treatment as recommended by the physician.

If you stop taking Ospolot, you may compromise the treatment success and the seizures may return.
Do not stop treatment without consulting the physician about it. Treatment duration and dosage may vary between patients and will be determined only by the attending physician**.**

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

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

4. <u>Side effects</u>

As with any medicine, the use of **Ospolot** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Please pay attention to those side effects which require you to contact a physician immediately and/or to stop treatment immediately, that are listed in the section "Before using this medicine" under the sub-heading "Special warnings regarding the use of this medicine".

<u>Very common side effects, effects occurring in more than 1 of 10 users:</u>

- gastrointestinal disturbances (such as nausea and vomiting)

<u>Common side effects, effects occurring in 1-10 of 100 users:</u>

- respiratory symptoms including shortness of breath (dose dependent)
- chest tightness, rapid heartbeats (palpitations)
- sensation of tingling in the limbs and in the face (dose dependent)
- dizziness, headache
- double vision
- hiccups, weight loss or loss of appetite

<u>Uncommon side effects, effects occurring in 1-10 of 1,000 users:</u>

- hallucinations, anxiety, lack of motivation, muscle weakness, joint pain
- increased number of seizures, grand-mal-status

<u>Side effects of unknown frequency (the frequency of these effects has not yet been established):</u>

- hypersensitivity reaction affecting several organ systems, including fever, skin rash, vasculitis, enlarged lymph nodes, joint pain, altered number of white blood cells, enlargement of the liver or spleen and severe skin reactions (Stevens-Johnson syndrome, Lyell syndrome)

- acute renal failure
- polyneuritis, significant deterioration of vision
- toxic reactions of the liver, abnormal levels of liver enzymes related to its function
- depressed mood/depression, behavioral changes such as aggressiveness, irritability, mood swings
- diarrhea

One patient is known, in whom administration of **Ospolot** led to progressive weakness of the limbs, hypersalivation, slurred speech and drowsiness up to loss of consciousness (coma).
These symptoms disappeared within hours after **Ospolot** treatment discontinuation.

Ospolot belongs to the group of carbonic anhydrase inhibitors causing side effects such as formation of renal stones and changes in blood composition (metabolic acidosis, haemodilution, changes in blood serum electrolyte values, such as decrease in blood calcium levels) and sensation of tiredness/ fatigue.

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

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! This medicine and any other medicine should be kept in a close place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.

Storage conditions:

- Do not store at a temperature above 25°C.
- Use the medicine within 12 weeks since opening.
- Keep the bottle tightly closed.
- Do not use the medicine if you notice that the color of the tablets has changed or if the tablets have swelled or seem more brittle.

6. Additional information

- In addition to the active ingredient sulthiame, the medicine also contains the following ingredients:
  maize starch, lactose monohydrate, talc, colloidal anhydrous silica, hypromellose, gelatin, magnesium stearate, macrogol 4000, titanium dioxide.
- **What does the medicine look like and what are the contents of the package:**
  Plastic or glass bottle containing 50 round, slightly curved, white film-coated tablets with a score line on one side and the number "200" on the other side.

  Not all pack sizes may be marketed.

- **Registration holder's name and address:** MegaPharm Ltd., P.O.B. 519, Hod Hasharon 4510501, Israel.

- **Manufacturer's name and address:** Desitin Arzneimittel GmbH, Hamburg, Germany.

- Revised in September 2020.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 066-04-28222.