**Package leaflet: Information for the patient**

# Ospolot® 20 mg/ml oral suspension

Sulthiame

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Ospolot is and what it is used for

Ospolot contains the active substance 'sulthiame', an antiepileptic medicine used for the treatment of a certain form of epilepsy in childhood called Rolandic epilepsy (also known as benign childhood epilepsy with centrotemporal spikes).

Treatment with Ospolot should only be performed by specialist paediatric neurologists who are experienced in epilepsy treatment.

## 2. What you need to know before taking Ospolot

**Do not give Ospolot if the child:**
- is allergic to sulthiame or similar medicines (sulphonamides), to sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217) or any of the other ingredients in this medicine (listed in section 6)
- has an overactive thyroid
- has high blood pressure
- has a metabolic condition called acute porphyria.

**Warnings and precautions**

Talk to your doctor before giving Ospolot,
- if the child has impaired kidney function,
- if the child is suffering from any psychiatric disorder.

Seek urgent medical advice if the child develops a fever, sore throat, rash with lymph node swelling and/or flu-like symptoms during treatment with Ospolot. These could be signs of an allergic, or other, reaction to the medicine which can become serious, in which case your doctor may decide to stop Ospolot.

Before treatment with Ospolot starts, blood tests will be carried out to check liver and kidney function. These will be repeated weekly for the first month of treatment then monthly up to six months after which they only need to be repeated two to four times a year.

A small number of patients being treated with anti-epileptics such as Ospolot have had thoughts of harming or killing themselves. If at any time such thoughts arise, immediately contact your doctor for advice.

**Other medicines and Ospolot**

Tell your doctor or pharmacist if the child is taking, has recently taken or might take any other medicines. Ospolot and the following medicines or groups of medicine may interact with each other during combined treatment.
- **Phenytoin:** Blood levels of phenytoin may be affected by Ospolot, especially if kidney function is reduced, so close monitoring will be carried out.
- **Lamotrigine:** Ospolot may increase lamotrigine blood levels. This will be carefully checked if this combination treatment is started.
- **Primidone:** This may worsen side-effects with Ospolot , particularly unsteadiness, dizziness and drowsiness.
- **Carbamazepine:** This may reduce levels of Ospolot in the blood.
- **Topiramate:** Side effects with Ospolot may be increased.
- **Acetazolamide:** Side effects with Ospolot may be increased.

**Ospolot with alcohol**

Alcohol should be avoided during treatment with Ospolot as it can cause unpleasant symptoms which may include flushing, a throbbing headache, nausea and vomiting, palpitations and blurred vision. The symptoms can sometimes be more serious and include difficulty breathing, disturbances in heart rhythm and a fall in blood pressure with possible collapse and loss of consciousness. Seizures may also occur.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

There is an increased risk that this medicine may harm your unborn baby. You should therefore not use this medicine during pregnancy unless it has been specifically prescribed by your doctor. If you are of childbearing age and are taking Ospolot, you must use an effective method of contraception. Do not interrupt your treatment with Ospolot before consulting with your doctor first. Any sudden discontinuation of treatment or unsupervised reduction of the dose may result in a return of epileptic seizures that may harm you and/or your unborn child.

Breast-feeding

It is not known whether the active substance contained in Ospolot passes into breast milk. For this reason, you should not take Ospolot while breast-feeding.

**Driving and using machines**

Even when used as directed, this medicine may affect your responsiveness to such an extent as to impair, for example, your ability to drive or use machines. In particular, this applies in combination with alcohol.

**Ospolot contains sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), sulphur dioxide (E220), sodium, fructose, glucose and sucrose**

Sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) may cause allergic reactions (possibly delayed).

Sulphur dioxide (E 220) may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains 0.0026 mg fructose in each ml.
Glucose and sucrose: if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Glucose, fructose and sucrose may be harmful to the teeth.

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say it is essentially 'sodium-free'.

## 3. How to take Ospolot

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose

Your doctor will usually start on a low dose, and gradually increase it over one week until the right dose is found (this is called the maintenance dose). The usual maintenance dose is 5 - 10 mg (0.25 – 0.5 ml) per kilogram of body weight per day, usually divided into three doses.

Table 1: dosing examples for a **starting dose of 2.5 mg sulthiame per kg per day**

| Patient-Weight | Starting dose: **2.5 mg* sulthiame per kg per day** | |
|---|---|---|
| | **Single dose (given 3 x daily)** | **Total daily dose** |
| **12 - 18 kg** | **0.5 – 0.75 ml** (equivalent to 10 – 15 mg sulthiame) | 1.5 – 2.25 ml (equivalent to 30 – 45 mg sulthiame) |
| **18 - 24 kg** | **0.75 -1.0 ml** (equivalent to 15 – 20 mg sulthiame) | 2.25 – 3.0 ml (equivalent to 45 – 60 mg sulthiame) |
| **24 - 30 kg** | **1.0 -1.25 ml** (equivalent to 20 – 25 mg sulthiame) | 3.0 – 3.75 ml (equivalent to 60 – 75 mg sulthiame) |
| **30 - 36 kg** | **1.25 – 1.5 ml** (equivalent to 25 – 30 mg sulthiame) | 3.75 – 4.5 ml (equivalent to 75 – 90 mg sulthiame) |
| **36 – and above** | **1.5 ml and above** (equivalent to 30 mg sulthiame and above) | 4.5 and above (equivalent to 90 mg sulthiame and above) |

*1 ml Ospolot oral suspension contains 20 mg sulthiame => 0.25 ml = 5 mg sulthiame

Table 2: dosing examples for a **maintenance dose of 5 mg sulthiame per kilogram per day:**

| Patient-Weight | Maintenance dose: **5 mg* sulthiame per kg per day** | |
|---|---|---|
| | **Single dose (given 3 x daily)** | Total daily dose |
| **12 - 18 kg** | **1.0 – 1.5 ml** (equivalent to 20 – 30 mg sulthiame) | 3.0 – 4.5 ml (equivalent to 60 – 90 mg sulthiame) |
| **18 - 24 kg** | **1.5 -2.0 ml** (equivalent to 30 – 40 mg sulthiame) | 4.5 – 6.0 ml (equivalent to 90 – 120 mg sulthiame) |
| **24 - 30 kg** | **2.0 -2.5 ml** (equivalent to 40 – 50 mg sulthiame) | 6.0 – 7.5 ml (equivalent to 120 – 150 mg sulthiame) |
| **30 - 36 kg** | **2.5 – 3.0 ml** (equivalent to 50 – 60 mg sulthiame) | 7.5 – 9.0 ml (equivalent to 150 – 180 mg sulthiame) |
| **36 – and above** | **3.0 ml and above** (equivalent to 60 mg sulthiame and above) | 9.0 and above (equivalent to 180 mg sulthiame and above) |

*1 ml Ospolot oral suspension contains 20 mg sulthiame => 0.25 ml = 5 mg sulthiame

Method and route of administration

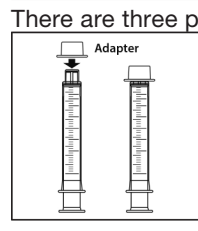
Ospolot is for oral use.

*Instructions for use*

Read these instructions carefully so that you know how to use this medicine.

**Components of the medicine kit**

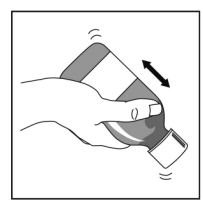
There are three parts to the medicine kit:




1. A plastic adapter
2. A 10 ml oral dosing syringe which fits into the plastic adapter.

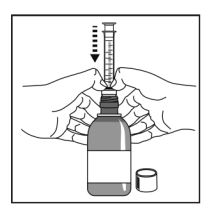
3. A bottle containing the oral suspension, with a child resistant cap. Always replace the cap after use.

**Preparing a dose of medicine**



1. Shake the bottle **vigorously for 30 seconds** in a bottom up position. If a sediment is detected at the bottom of the bottle, shake the bottle for another 30 seconds.
2. Open the child-resistant closure by **firmly** pressing it down and twisting it anti-clockwise (see top of cap).

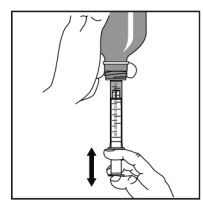
**Note:** Keep the cap nearby to close the bottle after each use.



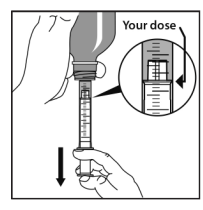
3. Hold the bottle upright on a table. Firmly push the plastic adapter with the oral syringe into the bottle opening, as far as you can.

**Note:** You may not be able to push the adapter down fully but it will be forced into the bottle when you screw the cap back on.

**After the first use the adapter remains in the bottle.**

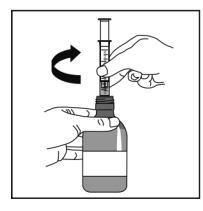


4. Hold the oral syringe firmly and turn the bottle upside down carefully. Slowly pull out the plunger, so that the oral syringe fills up with the suspension. Then completely push the plunger back, in order to remove any large air bubbles that might be inside the oral syringe.




5. Drawing the prescribed dose: Slowly pull out the syringe plunger, until the top of the wider part of the plunger is exactly on a level with the marker on the oral syringe barrel that indicates the prescribed dose.

Ask your pharmacist if you are unsure.



6. Carefully turn the bottle and oral syringe the right way up. Remove the oral syringe by gently twisting it out of the adapter. The adapter must always stay in the bottle.

7. Administer the dose directly into the mouth of the patient, who should be sitting in an upright position. Press the plunger **slowly** in order to allow for easy swallowing. The patient should drink a glass of water, juice or milk directly after intake.

Also, the dose can be mixed preferably with a **small** amount of water, or alternatively with orange juice, milk, yoghurt or wheat porridge just prior to administration. Do not take carbonated beverages or hot food with the suspension to avoid eructation or slowed swallowing. Stir and take the entire mixture right away.

8. Replace the child resistant cap after use, leaving the adapter in place.

9. Cleaning: After each use, rinse the syringe thoroughly with running water and wipe the outside with a dry, clean tissue.

Ospolot may be taken with or without food. Ideally the same routine should be followed each day.

Ospolot may also be given via a feeding tube which should be rinsed with at least 15 ml of water immediately after giving the medicine. If given this way, the dose should be prepared as for oral use immediately before administration.

How long should Ospolot be taken?

Anti-epileptic treatment is essentially long-term therapy. In each individual case, a paediatric neurologist experienced in the treatment of epilepsy should decide how to adjust the treatment, how long it should last and when it should be discontinued. Ospolot should not be stopped suddenly.

**If you give more Ospolot than you should**

Side-effects may be increased (see "Possible side effects", below). Seek urgent medical advice and show this medicine and leaflet if possible.

**If you forget a dose of Ospolot**

Do not take a double dose to make up for a forgotten dose. Take the dose at your next scheduled time, as prescribed by your doctor. Your treating physician should be informed.

**If you stop Ospolot**

If you wish to interrupt or stop treatment with Ospolot, discuss it with your doctor first. Do not stop treatment with this medicine

by yourself without medical advice, as it might cause the epileptic fits to return.

The length of treatment and the dose will vary depending on the individual patient and will be decided by your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common side effects (may affect more than 1 in 10 people):
- upset stomach (e.g. nausea, vomiting)

Common side effects (may affect up to 1 in 10 people):
- breathing difficulties
- chest tightness, palpitations or racing heart
- tingling in the arms, legs or face
- dizziness
- headache
- double vision
- hiccups
- loss of appetite
- weight loss

Uncommon side effects (may affect up to 1 in 100 people):
- hallucinations
- anxiety
- listlessness
- muscle weakness
- joint pain
- increased seizures, grand mal status

Not known (frequency cannot be estimated from the available data):
- delayed hypersensitivity reaction affecting several organ systems with fever, skin rash, inflamed blood vessels (vasculitis), lymph node swelling, abnormal white blood cell count, as well as enlarged liver or spleen and severe skin reactions (Stevens-Johnson syndrome, Lyell's syndrome)
- acute kidney failure
- significant deterioration of vision, polyneuritis (multiple nerve inflammation)
- toxic reactions on the liver and/or increased liver enzyme levels
- depressive mood/depression, personality changes, abnormal behaviour (e.g. aggressiveness, irritability, mood swings) and impaired cognitive ability
- diarrhoea

In one patient with long-standing treatment-resistant epilepsy, taking Ospolot led to increasing weakness of the limbs, increased salivation, slurred speech and increasing drowsiness to the point of coma. The symptoms resolved within hours after discontinuation of Ospolot.

The active ingredient in Ospolot (sulthiame) belongs to a group of medicines called 'carbonic anhydrase inhibitors' that have been associated with the formation of kidney stones, changes detected on certain blood tests and fatigue/exhaustion.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ospolot

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the carton after EXP. The expiry date refers to the last day of that month.

After first opening of the bottle do not use for longer than 3 months.

Do not use this medicine if you notice any damage to the bottle, closure or carton. Return the pack to your pharmacist.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Ospolot contains**
The active substance is sulthiame.

The other ingredients are: sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), sucralose, docusate sodium, xanthan gum, sodium dihydrogen phosphate dihydrate, dipotassium phosphate, strawberry flavour, sweetness modulator flavour (containing fructose, glucose, sucrose and sulphur dioxide (E220)), masking flavour, phosphoric acid 85%, purified water

**What Ospolot looks like and contents of the pack**
Ospolot is a white liquid with strawberry flavour.

The glass bottle with child-resistant closure contains 200 ml or 250 ml of Ospolot. It is packed in a cardboard box containing an oral syringe of 10 ml graduated every 0.25 ml and an adapter.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
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PBOspolot-GB