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, or pharmacist.
- 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 or pharmacist. 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 for the treatment of a certain form of epilepsy.

Ospolot is used to treat SeLECTS (Self-Limited Epilepsy with Centrotemporal Spikes) (former Rolandic epilepsy) in children and adolescents aged 3 years and above non responder/intolerant to other treatments or without other therapeutic alternatives.

2. What you need to know before you take Ospolot

Do not take Ospolot
- if you are allergic to sulthiame, other sulphonamides, or any of the other ingredients of this medicine (listed in section 6)
- if you have an overactive thyroid
- if you have high blood pressure
- if you have acute porphyria (a congenital or acquired disorder where your body is unable to produce enough red blood pigment).

Warnings and precautions
Talk to your doctor before taking Ospolot,
- if your kidney function is impaired,
- if you suffer from any psychiatric disorders.

Consult your treating physician immediately and have your blood counts checked if you notice allergic reactions with fever, sore throat, rash with lymph node swelling and/or flu-like symptoms during treatment with Ospolot. Your doctor may find it necessary to stop Ospolot if you get severe allergic reactions.

Initial checks on blood counts, liver enzymes and kidney function are recommended before treatment with Ospolot, at weekly intervals in the first month of treatment and then at monthly intervals thereafter. After six months of treatment, two to four check-ups per year are sufficient.

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

Other medicines and Ospolot
Tell your doctor or pharmacist if you are taking, have 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.

Combination of Ospolot with medicines to treat epilepsy:
- **Phenytoin**: Blood levels of phenytoin may increase significantly. This combination requires close monitoring. Your doctor will therefore carry out frequent checks on your phenytoin blood levels, especially if your kidney function is impaired.
- **Lamotrigine**: In individual cases, there may be an increase in lamotrigine levels in the blood. Your lamotrigine blood levels should therefore be monitored more frequently at the start of such combination treatment.
- **Primidone**: Side effects of Ospolot may be enhanced. In particular, it may cause unsteady gait, dizziness and drowsiness.
- **Carbamazepine**: There are indications of a reduction in the blood levels of sulthiame when taken at the same time as carbamazepine.

When sulthiame is taken at the same time as other carbonic anhydrase inhibitors (e.g. topiramate used to treat epilepsy and migraine or acetazolamide used to treat increased inner eye pressure), the risk of side effects may be increased due to carbonic anhydrase inhibition.

Ospolot with alcohol
During treatment with Ospolot, you should not drink alcohol, as alcohol can unpredictably alter and enhance the effect of Ospolot.
Ospolot, in interaction with alcohol, may also cause a very unpleasant reaction in some cases, with dilation of the blood vessels, throbbing headache, respiratory distress, nausea, vomiting, racing heart, drop in blood pressure, blurred vision, confusion, shock reactions, heart rhythm disorders, unconsciousness and seizures. These symptoms may vary greatly in nature and duration.

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.

<u>Pregnancy</u>
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. 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.

<u>Breast-feeding</u>
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 essentially 'sodium-free'.

3. How to take Ospolot

Ospolot should be initiated and supervised by physicians with experience in the treatment of epilepsy.

Always take 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 you on a low dose, and gradually increase the dose over one week until you reach a dose that works for you (called maintenance dose). The usual maintenance dose is 5- 10 mg (0.25 – 0.5 ml) per kilogram of body weight and day.

Preferably the daily dose is divided into three single doses.

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

Patient-Weight	Starting dose: **2.5 mg* sulthiame per kg and 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 and day**:

Patient-Weight	Maintenance dose: **5 mg*sulthiame per kg and 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

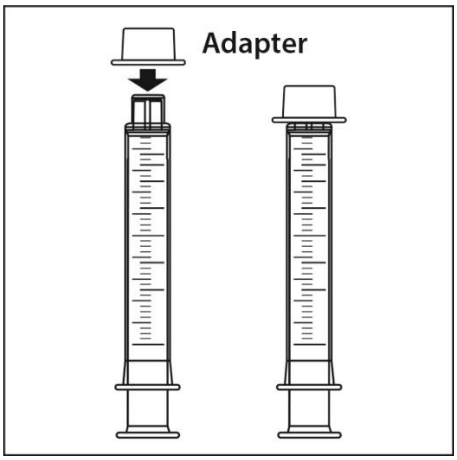
Note: For single doses of 10 ml or more tablets may be used.

Method and route of administration
Ospolot is for oral use.

Ospolot may be swallowed directly from the oral syringe, or
Ospolot may be drunk right away after mixing preferable with a small volume of water, alternatively with orange juice, milk, yoghurt or wheat porridge, or
Ospolot may be administered via a feeding tube.
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:

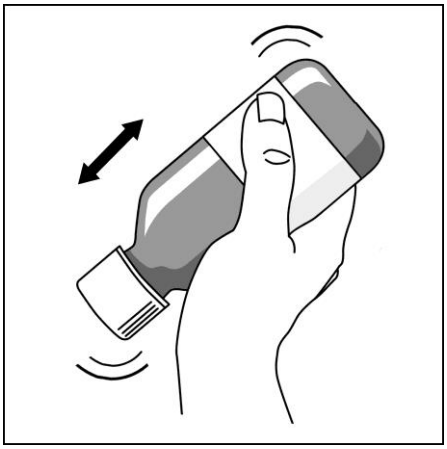


1. A plastic adapter

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

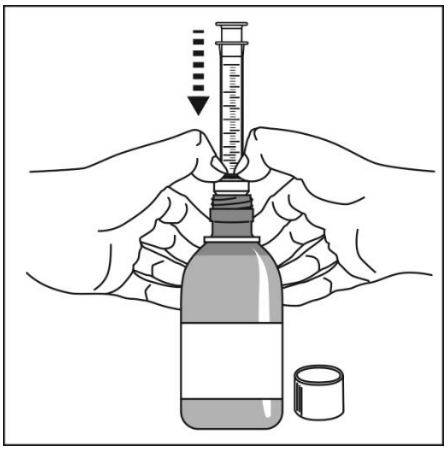
3. A bottle containing the oral suspension, with a child resistant closure. Always replace the cap after use.

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).

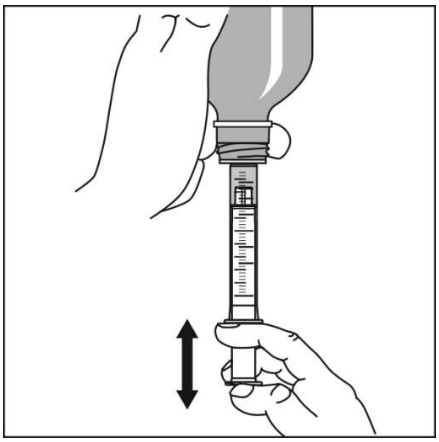
   Note: Keep the closure nearby to close the bottle after each use.



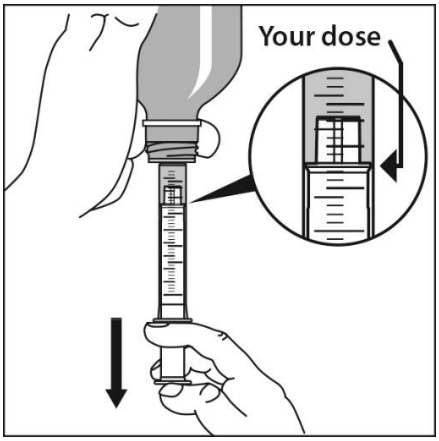
3. Hold the bottle upright on a table. Firmly push the plastic adapter with the oral syringe into the bottle opening, as far as you can.

   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.

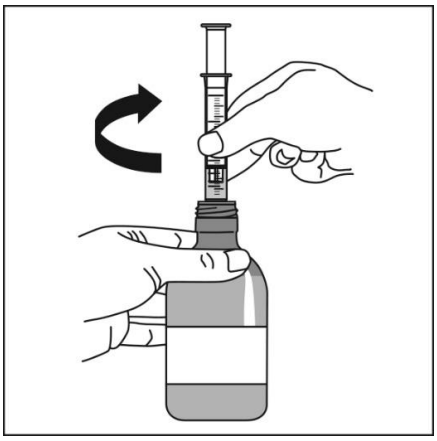


4. Hold the oral syringe firmly and turn the bottle upside down carefully. Slowly pull out the plunger, so that the oral syringe fills up with the suspension. Then completely push the plunger back, in order to remove any large air bubbles that might be inside the oral syringe.



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.

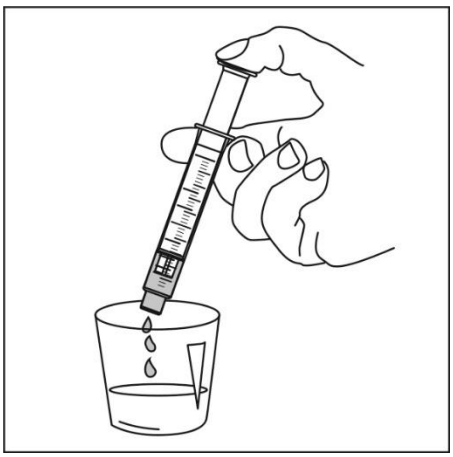
   Ask your pharmacist if you are unsure.



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 closure 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.

You can take Ospolot with food, but also independently of meals. If possible, you should always maintain your Ospolot-taking routine.

The oral suspension may also be administered via a feeding tube that should be rinsed with minimum 15 ml of water immediately after administration. If this method of administration is used, the dose should be prepared as described above immediately before administration.

How long should you take Ospolot?
Antiepileptic treatment is essentially long-term therapy. In each individual case, a paediatric neurologist (neuropaediatric) 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 take more Ospolot than you should
The side effects mentioned under "Possible side effects" may be enhanced. In case of overdose, a doctor/emergency doctor should be consulted as soon as possible and, if possible, you should show him/her the medicine and this package leaflet.

If you forget to take 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 taking Ospolot
If you wish to interrupt or end treatment with Ospolot, discuss it with your doctor first. Do not stop treatment with this medicine by yourself without medical advice, as it might endanger the success pf treatment and may cause the epileptic fits to return. The duration of treatment varies depending on the individual and will be decided by your doctor.

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

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 and even respiratory distress (dose-dependent)
- chest tightness, racing heart
- tingling in the arms, legs or face (dose-dependent)
- dizziness, headache
- double vision
- hiccups, weight loss or loss of appetite

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, joint pain, abnormal white blood cell count, as well as enlarged liver or spleen and severe skin reactions (Stevens-Johnson syndrome, Toxic Epidermal Necrolysis)
- acute kidney failure
- deterioration of vision, that may be significant, 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.

Sulthiame belongs to an active substance group (carbonic anhydrase inhibitors) that can lead to the formation of kidney stones, changes in blood composition (metabolic acidosis, haemodilution and changes in serum electrolyte levels such as reduced blood calcium levels) as well as fatigue/exhaustion.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. 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.

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 para hydroxybenzoate (E219), sodium propyl para hydroxybenzoate (E217), sucralose (E955), docusate sodium, xanthan gum (E415), sodium dihydrogen phosphate dihydrate (E339), dipotassium phosphate (E340), strawberry flavour (containing Acacia E414), sweetness modulator flavour (containing fructose, glucose, sucrose, sulphur dioxide (E220)), masking flavour (containing Sucralose E955, Maltodextrin (potatoe)), phosphoric acid 85% (E338) (for pH adjustment), purified water

What Ospolot looks like and contents of the pack

Ospolot oral suspension is a white suspension.

The glass bottle with child-resistant closure contains 200 ml or 250 ml of oral suspension. 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

Desitin Arzneimittel GmbH
Weg beim Jäger 214
22335
Hamburg
Germany
E-mail: medinfo@desitin.ie

Manufacturers

Desitin Arzneimittel GmbH
Weg beim Jäger 214
22335
Hamburg
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

BE	Ospolot 20 mg/ml suspensie voor oraal gebruik / solution buvable / Suspension zum Einnehmen
CZ	Ospolot
DK	Ospolot
DE	Ospolot 20 mg/ml Suspension zum Einnehmen
EE	Ospolot
ES	Ospolot 20 mg/ml Suspensión oral
FI	Ospolot 20 mg/ml Oraalisuspensio
IE	Ospolot 20 mg/ml oral suspension
IT	Ospolot
LU	Ospolot
NL	Ospolot 20 mg/ml Suspensie voor oraal gebruik
NO	Ospolot 20 mg/ml Mikstur, suspensjon
PL	Sultiame Desitin
PT	Ospolot 20 mg/ml Suspensão oral
RO	Ospolot 20 mg/ml Suspensie orală
SE	Ospolot 20 mg/ml Oral suspension
SK	Ospolot

This leaflet was last revised in 03/2025.
