

Ospolot® Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ospolot Tablets?

Ospolot Tablets contains the active ingredient sulthiame. Ospolot Tablets are used to control epilepsy. Epilepsy is a condition where you have repeated seizures or fits.

For more information, see Section [1. Why am I using Ospolot Tablets?](#) in the full CMI.

2. What should I know before I use Ospolot Tablets?

Do not use if you have ever had an allergic reaction to Ospolot Tablets or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ospolot Tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ospolot Tablets and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ospolot Tablets?

Your doctor will tell you how many tablets to take, and when to take them each day.

Follow all directions given to you by your doctor or pharmacist carefully. If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

More instructions can be found in Section [4. How do I use Ospolot Tablets?](#) in the full CMI.

5. What should I know while using Ospolot Tablets?

Things you should do	<ul style="list-style-type: none"> Remind any doctor, dentist, pharmacist or nurse you visit that you are taking Ospolot Tablets. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Ospolot Tablets. If you become pregnant while taking Ospolot Tablets, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none"> Be careful driving or operating machinery until you know how Ospolot Tablets affect you.
Drinking alcohol	<ul style="list-style-type: none"> Do not drink alcohol while you are being treated with Ospolot Tablets.
Looking after your medicine	<ul style="list-style-type: none"> Store in a cool dry place, below 30°C. Keep your tablets in the bottle until it is time to take them. Do not store Ospolot Tablets or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car. Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using Ospolot Tablets?](#) in the full CMI.

6. Are there any side effects?

Ospolot Tablets may cause weakness, unsteadiness when walking, reduced co-ordination or slowed reactions, rapid breathing, shortness of breath, difficulty breathing, change in heartbeat, changes in appetite, changes in your weight, numbness or tingling face, hands and feet, fainting, giddiness, skin rash, nausea or vomiting, stomach pain, cramps, headache and double vision.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ospolot[®] Tablets

Active ingredient: *sulthiame*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ospolot Tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ospolot Tablets.**

Where to find information in this leaflet:

1. [Why am I using Ospolot Tablets?](#)
2. [What should I know before I use Ospolot Tablets?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Ospolot Tablets?](#)
5. [What should I know while using Ospolot Tablets?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Ospolot Tablets?

Ospolot Tablets contains the active ingredient sulthiame.

Ospolot Tablets belongs to a group of medicines called sulfonamides. These medicines are thought to work by controlling brain chemicals that send signals to nerves so that seizures do not happen.

Ospolot Tablets are used to control epilepsy. Epilepsy is a condition where you have repeated seizures or fits. There are many different types of seizures, ranging from mild to severe.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use Ospolot Tablets?

Warnings

Do not drink alcohol while you are being treated with Ospolot Tablets.

Do not use Ospolot Tablets if you are allergic to:

- any medicine containing sulthiame, or any of the ingredients listed at the end of this leaflet.
- any other similar medicines such as sulfonamides.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

You should not take this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have allergies to any medicines, food, preservatives, or dyes.
- have or have had the following medical conditions:
 - kidney problems
 - depression

If you are not sure whether you should start taking Ospolot Tablets talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor can discuss with you the risk and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Ospolot Tablets.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket, health food shop, herbalist or naturopath.

Some medicines may interfere with Ospolot Tablets and affect how they work. These include:

- other medicines used to treat fits and convulsions such as primidone and phenytoin
- phenobarbitone, carbamazepine, lamotrigine, a medicine used to sedate people or control convulsions
- medicines used to treat eye conditions or control convulsions such as carboanhydrase-inhibitors.

These medicines may be affected by Ospolot Tablets or may affect how well Ospolot Tablets work. You may need different amounts of your medicines, or you may need to take difference medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ospolot Tablets.

4. How do I use Ospolot Tablets?

How much to take

- Your doctor will tell you how many tablets to take and when to take them each day. This may depend on your age, your condition and whether or not you are taking other medicines.
- Your doctor may recommend that you start with a low dose of Ospolot Tablets and slowly increase the dose to the lowest amount needed to control your epilepsy.
- **Follow all directions given to you by your doctor or pharmacist carefully.** It may differ from the information contained in the leaflet.
- **If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.**

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

How to take Ospolot Tablets

Swallow the tablets whole with a glass of water.

When to take Ospolot Tablets

- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- **Take Ospolot immediately after a meal, at about the same time each day.** If you take it on an empty stomach, it may cause a stomach upset.
- **Continue taking your medicine for as long as your doctor tells you to.** Ospolot Tablets help control your condition but do not cure it. Therefore, you must take your medicine every day, even if you feel well.

Most anticonvulsant medicines take time to work, so do not be discouraged if you do not feel better straight away.

- **Do not stop taking Ospolot or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.**

Stopping this medicine suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you forget to use Ospolot Tablets

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine or not sure what to do, ask your doctor or pharmacist for some hints.

If you use too many Ospolot Tablets

If you think that you have used too much Ospolot Tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- vomiting
- headache
- dizziness, light-headedness
- spinning sensation
- unsteadiness when walking
- increased rate or abnormal breathing.

5. What should I know while using Ospolot Tablets?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ospolot Tablets.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking Ospolot Tablets.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Ospolot Tablets. It may affect other medicines used during surgery.

Tell your doctor if you have any changes in mood or behaviour or have thoughts about harming yourself. This medicine may increase the risk of suicidal thoughts and behaviours.

If you need to have any blood tests, tell your doctor that you are taking Ospolot Tablets. It may affect the results of some tests.

Keep all your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure this medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- become pregnant during the course of treatment with Ospolot Tablets.

Remind any doctor, dentist, pharmacist, or nurse you visit that you have been given Ospolot Tablets.

Things you should not do

- Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen.
- Do not take Ospolot Tablets to treat any other complaints unless your doctor tells you to.
- Do not give Ospolot Tablets to anyone else, even if they have the same condition as you.
- Do not drink alcohol while taking Ospolot Tablets.

Driving or using machines

Be careful driving or operating machinery until you know how Ospolot Tablets affect you.

This medicine may cause dizziness in some people. If you have any of these symptoms do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- Keep your tablets in the bottle until it is time to take them. If you take the tablets out of the bottle they will not keep well.
- Keep your tablets in a cool dry place where the temperature stays below 30°C.
- Do not store Ospolot Tablets or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.
- Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<p>Musculoskeletal related:</p> <ul style="list-style-type: none"> • weakness <p>Respiratory related:</p> <ul style="list-style-type: none"> • rapid breathing • shortness of breath • difficulty breathing <p>Cardiovascular related:</p> <ul style="list-style-type: none"> • change in heartbeat <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • changes in appetite • changes in body weight <p>Nervous system related:</p> <ul style="list-style-type: none"> • numbness or tingling face, hands and feet • fainting • unsteadiness when walking • reduced co-ordination or slowed reactions 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>This list includes the more common side effects of your medicine.</p>

Serious side effects

Serious side effects	What to do
<p>Nervous system:</p> <ul style="list-style-type: none"> • giddiness • headache • sleeplessness (insomnia) • unusual changes in mood or behaviour • symptoms of depression which may include: <ul style="list-style-type: none"> – sadness – loss of interest or pleasure in activities you used to enjoy – change in weight – difficulty in sleeping, or oversleeping – energy loss – feelings of worthlessness – thoughts of death <p>Skin related:</p> <ul style="list-style-type: none"> • skin rash <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • nausea or vomiting • stomach pain, cramps or discomfort • increased saliva <p>Eye related:</p> <ul style="list-style-type: none"> • double vision <p>Musculoskeletal related:</p> <ul style="list-style-type: none"> • increased pain 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Very serious side effects

Very serious side effects	What to do
<p>Nervous system:</p> <ul style="list-style-type: none"> • suicidal thoughts • behaviour, or thoughts about self-harm • more frequent or more severe seizures or fits • a series of rapidly repeated seizures without gaining consciousness • severe depression • recurrence of a previous mental illness. <p>Skin related:</p> <ul style="list-style-type: none"> • severe skin blisters and bleeding in the lips, eyes, mouth, nose and genitals <p>Other:</p> <ul style="list-style-type: none"> • fever • severe chills • sore throat or mouth ulcers 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These side effects are very rare.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some of these side effects such as changes in the levels of calcium and vitamin D can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ospolot Tablets contain

Active ingredient (main ingredient)	sulthiame 50 mg or 200 mg per tablet.
Other ingredients (inactive ingredients)	maize starch lactose monohydrate purified talc colloidal anhydrous silica gelatin magnesium stearate hypromellose macrogol 4000 titanium dioxide
Potential allergens	sugars as lactose.

Ospolot, Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.

Do not take this medicine if you are allergic to any of these ingredients.

Ospolot Tablets do not contain sucrose, gluten, tartrazine, or any other azo dyes.

What Ospolot Tablets look like

Ospolot 50 mg contains 50 mg tablets that are white, round, film-coated and debossed 50 on one side, plain on the reverse side.

Ospolot 200 mg contains 200 mg tablets that are white, round, film-coated and debossed 200 on one side and scored on the reverse side.

Ospolot 50 mg tablets and Ospolot 200 mg tablets are supplied in HDPE (High Density Polyethylene) bottles with a PP (polypropylene) child resistant cap (200 tablets/bottle).

Ospolot tablets comes in the following strengths:

OSPOLOT sulthiame 50 mg tablet bottle AUST R 18847

OSPOLOT sulthiame 200 mg tablet bottle AUST R 18848

Who distributes Ospolot Tablets

Ospolot Tablets are supplied in Australia by:

Phebra Pty Ltd
19 Orion Road, Lane Cove West,
NSW 2066, Australia.