

Serepax®

oxazepam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Serepax. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Serepax against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Serepax is used for

Serepax is used to treat

- Anxiety
- Tremor, confusion or anxiety associated with alcohol withdrawal.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

Serepax contains the active ingredient oxazepam, a benzodiazepine. It is thought to work by acting on the brain chemicals.

In general, benzodiazepines should be taken for short periods only (for example 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

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

Before you take it

When you must not take it

Do not take SEREPAX if you are allergic to:

- Oxazepam or any other benzodiazepine medicines
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take this medicine if you have:

- severe and chronic lung disease or breathing difficulties
- sleep apnoea

Do not take it if the packaging shows signs of tampering or the tablets do not look quite right.

Do not take it if the expiry date (EXP) printed on the pack has passed.

Serepax is not recommended for use in children under 16 years of age, as its safety and effectiveness have not been established in this age group.

Before you take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Like other benzodiazepine medicines, Serepax may cause unwanted effects in the newborn baby if used during pregnancy. Your doctor will

discuss the risks and benefits of taking this medicine during pregnancy.

Tell your doctor you are breastfeeding or wish to breastfeed.

Serepax may pass into breast milk and cause drowsiness and feeding difficulties in the baby. Your doctor will discuss the risks and benefits of taking Serepax when breastfeeding.

Tell your doctor if you have any medical conditions, especially the following:

- liver, kidney or lung problems
- epilepsy, fits or convulsions
- severe muscle weakness known as myasthenia gravis
- low blood pressure
- glaucoma (increased pressure in the eye)
- depression, psychosis or schizophrenia
- drug or alcohol dependence or a past history of these problems.

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you drink alcohol regularly. Alcohol may increase the effects of Serepax.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you take any medicine.

Taking other medicines

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

Some medicines may interfere with Serepax. These include:

- other sleeping tablets, sedatives or tranquillisers
- medicines for depression, schizophrenia and other mental illnesses
- medicines to treat epilepsy and fits
- medicines for allergies, for example antihistamines or cold tablets
- medicines used to treat parkinson's disease
- muscle relaxants
- some pain relievers

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

The dose will vary from patient to patient.

Your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Swallow Serepax with a glass of water.

This medicine can be taken with or without food.

How long to take it

Take Serepax only for as long as your doctor recommends.

It is usually used for short periods only (such as 2 to 4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

If you forget to take it

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 it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Serepax. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Serepax you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are using it

Things you must do

Take Serepax exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while you are taking it, tell your doctor immediately.

Visit your doctor regularly so they can check on your progress.

Your doctor will check your condition to see whether you should continue to take it.

Tell your doctor if you feel this medicine is not helping your condition.

If you have to have any blood tests, tell your doctor that you are taking Serepax.

It may affect the results of some tests.

Keep enough of your medicine to last weekends and holidays.

Things you must not do

Do not drive or operate machinery until you know how Serepax affects you.

It may cause drowsiness or dizziness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Do not take it for a longer time than your doctor has prescribed.

Do not stop taking it or change the dose, without first checking with your doctor.

Stopping Serepax suddenly may cause some unwanted effects. Your doctor may want you to gradually reduce the amount you are taking

before stopping completely. This may help reduce the possibility of unwanted side effects.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give it to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when drinking alcohol.

Combining Serepax and alcohol can make you more sleepy, dizzy or lightheaded.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking this medicine.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Serepax.

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- dizziness, drowsiness, feeling tired
- lightheadedness or feeling faint
- headache
- nausea, stomach pain
- unpleasant dreams
- slurred speech
- blurred vision
- tingling or numbness of the hands or feet

Tell your doctor immediately if you notice any of the following:

- confusion
- behavioural or mood changes such as sudden outbursts of anger and increased excitement
- hallucinations
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- yellowing of the eyes and skin (jaundice)
- dark coloured urine

The above list includes serious side effects which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- fainting
- any type of skin rashes, itching or hives
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath

The side effects listed above are serious and require urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Serepax, or any other medicines, in the bathroom or near a sink. Do not leave it in the car or on window sills.

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.

Disposal

If your doctor tells you to stop taking Serepax or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

Serepax tablets are available in 2 strengths.

- Serepax 15 - white, round tablets, one face convex marked "15" and the opposite face flat with Ezi-split breakline.
- Serepax 30 - orange, round tablets, one face convex marked "30" and the opposite face flat with Ezi-split breakline.

Each pack contains 25 tablets.

Ingredients

The active ingredient in SEREPAX tablets is oxazepam.

Each SEREPAX 15 mg tablet contains 15 mg oxazepam.

Each SEREPAX 30 mg tablet contains 30 mg oxazepam.

SEREPAX 15 mg also contains the following excipients: magnesium stearate, microcrystalline cellulose, polacrillin potassium and lactose.

SEREPAX 30 mg also contains the following excipients: magnesium stearate, methyl cellulose, polacrillin potassium and lactose, Sunset Yellow CI 15985 as a colouring agent.

SEREPAX does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

SEREPAX is supplied in Australia by:

Aspen Pharma Pty Ltd.
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Numbers:

SEREPAX 15 - AUST R 174675

SEREPAX 30 - AUST R 10417

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