

SEREPAX

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 SEREPAX?

SEREPAX contains the active ingredient oxazepam. SEREPAX is used to treat anxiety, tremor, confusion or anxiety associated with alcohol withdrawal.

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

2. What should I know before I use SEREPAX?

Do not use if you have ever had an allergic reaction to SEREPAX 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 SEREPAX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEREPAX 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 SEREPAX?

- The dose will vary between patients. Your doctor will tell you how many tablets you need to take each day and when to take them.
- Swallow SEREPAX with a glass of water, with or without food.
- Take SEREPAX only for as long as your doctor recommends. It is usually used for short periods only (such as 2 to 4 weeks).

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

5. What should I know while using SEREPAX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SEREPAX.• Take SEREPAX exactly as your doctor has prescribed.• If you become pregnant while you are taking it, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change the dose, without first checking with your doctor.• Do not take it for a longer time than your doctor has prescribed.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how SEREPAX affects you.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol• Combining SEREPAX and alcohol can make you more sleepy, dizzy or lightheaded.
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in a cool dry place where the temperature stays below 30°C• 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.

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

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SEREPAX. Some mild side effect include dizziness, drowsiness, feeling tired, lightheadedness or feeling faint and headache. Some serious side effects include confusion, behavioural or mood changes such as sudden outbursts of anger and increased excitement and hallucinations.

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

SEREPAX

Active ingredient(s): *oxazepam*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEREPAX. **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 SEREPAX.**

Where to find information in this leaflet:

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

1. Why am I using SEREPAX?

SEREPAX contains the active ingredient oxazepam.

SEREPAX is a benzodiazepine which is thought to work by acting on the brain chemicals.

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.

2. What should I know before I use SEREPAX?

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.

Warnings

Do not use SEREPAX if:

- you are allergic to oxazepam, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have severe and chronic lung disease or breathing difficulties.
- you have sleep apnoea.
- the expiry date (EXP) printed on the pack has passed.
- the packaging shows signs of tampering or the tablets do not look quite right.

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.

Check with your doctor if you:

- take any medicines for any other condition.
- 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 history of these problems.
- are allergic to any other medicines, foods, dyes or preservatives.
- are pregnant or plan to become pregnant.
- are breastfeeding or wish to breastfeed.
- drink alcohol regularly. Alcohol may increase the effects of SEREPAX.
- plan to have surgery.

Suddenly stopping SEREPAX in patients with epilepsy can cause a temporary increase in the number and severity of seizures.

Your doctor may have prescribed SEREPAX for depression or psychosis. SEREPAX is not recommended as the first choice of treatment for depression and psychosis. It may increase depression, worsen mental illness, suicidal thoughts and actions.

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

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.

SEREPAX should not be used during pregnancy.

It should be avoided during the first trimester of pregnancy as it may increase the risk of defects present at birth.

It may cause unwanted effects in the newborn baby if taken during the late phase of pregnancy or during childbirth, such as low muscle strength, shallow breathing and feeding problems.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children under 16 years of age

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with SEREPAX and affect how it works.

- 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

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

4. How do I use SEREPAX?

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.

When to take/use SEREPAX

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.

How to take SEREPAX

- Swallow SEREPAX with a glass of water.
- This medicine can be taken with or without food.

If you forget to use SEREPAX

SEREPAX should be used regularly at the same time each day.

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 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 use too much SEREPAX

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

If you take too much SEREPAX you may feel drowsy, confused, tired, dizzy, have low muscle strength, low blood pressure, difficulty breathing, lack of coordination, feel weak or become unconscious. It can be rarely fatal.

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.

5. What should I know while using SEREPAX?

Things you should do

- Take SEREPAX exactly as your doctor has prescribed.
- 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.
- If you 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.

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.

Call your doctor straight away if you:

- Become pregnant while you are taking it, tell your doctor immediately.
- Feel this medicine is not helping your condition.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Remind any doctor, dentist or pharmacist you visit that you are using SEREPAX.

Things you should not do

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

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

Stopping SEREPAX suddenly may cause some unwanted withdrawal effects. It is more common in patients that have received high doses over longer periods of time.

Withdrawal symptoms include insomnia, anxiety, unusual mood, panic attacks, dizziness, light sensitivity, confusion, seeing or hearing things that are not real (hallucinations), vomiting, sweating, fits (convulsions), a feeling of loss of identity/feeling detached from yourself (depersonalisation or derealisation) and loss of short-term memory.

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol regularly.

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.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• 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	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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 <p>The very serious side effects below may require urgent medical attention. Go straight to the Emergency Department at your nearest hospital.</p> <p>Very Serious Side Effects:</p> <ul style="list-style-type: none">• 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	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.

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.

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 SEREPAX contains

Active ingredient (main ingredient)	Each SEREPAX 15 mg tablet contains 15mg oxazepam. Each SEREPAX 30 mg tablet contains 30mg oxazepam.
Other ingredients (inactive ingredients)	SEREPAX 15 mg contains the following excipients: magnesium stearate, microcrystalline cellulose, polacrillin potassium and lactose monohydrate. SEREPAX 30 mg contains the following excipients: magnesium stearate, methyl cellulose, polacrillin potassium and lactose monohydrate, Sunset Yellow CI 15985 as a colouring agent.
Potential allergens	Lactose

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

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

What SEREPAX 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.

Australian Registration Numbers:

SEREPAX 15 - AUST R 174675

SEREPAX 30 - AUST R 10417

Who Supplies SEREPAX

Aspen Pharma Pty Ltd

34-36 Chandos Street

St Leonards NSW 2065

Australia

This leaflet was prepared in October 2022.