

SERENACE tablets and oral liquid

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 SERENACE?

SERENACE contains the active ingredient haloperidol. It is used to treat various mental illnesses, as well as nausea and vomiting in certain situations.

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

2. What should I know before I use SERENACE?

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

3. What if I am taking other medicines?

Some medicines may interfere with SERENACE 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 SERENACE?

- Your doctor will tell you how much you will need to take each day. Continue using it until your doctor tells you to stop.
- Tablets: Swallow with a glass of water.
- Oral liquid: Shake the bottle well and accurately measure the dose with a medicine measure.
- It does not matter if you take SERENACE before or after food.

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

5. What should I know while using SERENACE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SERENACE.• Protect yourself from sunlight when going outdoors. Do not use a sun lamp or tanning bed or booth.• Make sure you keep cool in hot weather and keep warm in cool weather.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking SERENACE, or lower the dosage, even if you are feeling better, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how SERENACE affects you.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking SERENACE. It may exacerbate feelings of dizziness, light-headedness, and drowsiness. Your doctor may suggest avoiding alcohol while taking SERENACE,
Looking after your medicine	<ul style="list-style-type: none">• Keep SERENACE in the original packaging until it is time to use it.• Keep it in a cool dry place, away from light where the temperature stays below 30°C.

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

6. Are there any side effects?

More common side effects of SERENACE are usually mild and short-lived. These include drowsiness or tiredness; restlessness, agitation, anxiety or excitement; muscle weakness; difficulty in speaking and/or swallowing; and increased or decreased sweating. Serious side effects or signs of serious side effects include: very high fever; symptoms of sunburn which occur more quickly than normal; changes in breathing; changes in heartbeat; anaemia; yellowing of skin and/or eyes; unusual or uncontrolled movements in the body or tongue/face (e.g. trembling, shaking, twisting movements, shuffling walk, and stiffness or arms and legs); muscle spasms; fits or seizures; and an allergic reaction.

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

SERENACE tablets and oral liquid

Active ingredient: *haloperidol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SERENACE.

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 SERENACE.

Where to find information in this leaflet:

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

1. Why am I using SERENACE?

SERENACE contains the active ingredient haloperidol. It belongs to a group of medicines called antipsychotics.

SERENACE helps to correct chemical imbalances in the brain, which may cause mental illness. These chemicals may also affect the parts of the brain, which control nausea and vomiting.

It is used to treat mental illnesses such as:

- schizophrenia, an illness with disturbances in thinking, feelings and behaviour
- mania, an illness where the patient experiences episodes of overactivity, elation or irritability
- severe anxiety, tension or excitement and severe agitation, hyperactivity or aggression in patients with mental or emotional illness.

It is also used to treat:

- behavioural problems in children with mental retardation or mental illness
- nausea and vomiting (caused by cancer treatment)
- anxiety and pain during surgery (neurolept anaesthesia)
- Tourette's Syndrome, a condition with uncontrolled vocal outbursts and body movements (tics)

Before you receive SERENACE, your doctor may recommend that you have an electrocardiogram or ECG. Your doctor may also recommend that you have an ECG on a regular basis while taking SERENACE.

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

Your doctor may have prescribed SERENACE for another reason.

There is no evidence that this medicine is addictive.

2. What should I know before I use SERENACE?

Warnings

Do not use SERENACE if:

- **you are allergic to haloperidol or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- **you have or have had any of the following medical conditions:**
 - brain damage
 - Parkinson's disease
 - severe depression
 - alcohol or drug intoxication
 - spasticity, where a group of muscles are stiff and restricted in movement.
 - Parkinsonian-like symptoms together with senility
 - breast cancer.
- **the expiry date printed on the pack has passed**
- **the packaging is torn or shows signs of tampering.**

SERENACE should not be given to anyone who is unconscious or in a coma.

Check with your doctor if:

- **you are taking any other medicines**
- **you have or have had any other medical conditions, especially the following:**
 - tumour of the pituitary gland, a small gland at the base of the brain
 - brain tumour
 - kidney problems
 - difficulty passing urine
 - heart and blood vessel problems
 - fast or irregular heartbeats (arrhythmia)
 - liver disease
 - disease of the blood with a reduced number of red or white blood cells or platelets
 - prostate problems
 - breast cancer or a family history of breast cancer
 - breathing difficulties (asthma, emphysema, respiratory infections, silent pneumonia)
 - paralytic ileus, a condition where the small bowel does not work properly
 - blockage in your intestines
 - epilepsy, seizures or fits
 - diabetes
 - low blood pressure
 - sleep apnoea

- an overactive thyroid gland
- glaucoma, a condition in which there is usually a build-up of fluid in the eye
- eye problems, such as diseases of the retina or blurred vision
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaws which may progress to the arms and legs
- pheochromocytoma, a rare tumour of the adrenal gland which is near the kidneys
- alcoholism or drug dependence.
- **you have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.**
- **you will be in a hot environment or do a lot of vigorous exercise.**
SERENACE may make you sweat less, causing your body to overheat.
- **you smoke.**
Nicotine can affect the amount of haloperidol in your body. A sudden change in your usual smoking habits can also change the effects of haloperidol.

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

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

Like most antipsychotic medicines, SERENACE is not recommended for use during pregnancy. However, if you need to take SERENACE during your pregnancy, your doctor will discuss the risks and benefits involved in taking it.

Tell your doctor if you are breastfeeding or plan to breast-feed.

It is not recommended for use while breast feeding as it may pass into breast milk.

Use in children

SERENACE should not be given to children under 12 years of age, unless directed by the child's doctor.

SERENACE is not recommended for use in children under the age of 3 years, as there is not enough information on its effects 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 SERENACE and affect how it works. These include:

- alcohol
- nicotine or tobacco smoke
- pain killers
- benzodiazepines and other medicines used to treat anxiety or to help you sleep
- medicines used to treat hay fever, coughs and colds
- anticonvulsants, medicines used to control epilepsy
- medicines used to control depression or mood swings e.g. fluoxetine, fluvoxamine, nefazodone, paroxetine, venlafaxine, lithium, carbamazepine
- antipsychotic medicines, used to treat mental illnesses
- medicines used to treat high blood pressure (hypertension) and heart conditions
- medicines used to treat fast or irregular heartbeats (arrhythmia)
- medicines used to treat Parkinson's disease
- anticholinergic medicines, used to prevent travel sickness, relieve stomach cramps or treat Parkinson's disease
- anticoagulants, medicines used to prevent blood clots e.g. warfarin
- medicines used as appetite suppressants
- tacrine, medicine used to treat dementia in Alzheimer's disease
- stimulants such as amphetamine
- adrenaline, a medicine used in emergency situations
- rifampicin, antibiotic used to treat infections.

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

4. How do I use SERENACE?

How much to take

Follow all directions given to you by your doctor or pharmacist.

They will tell you how much SERENACE you will need to take each day. This depends on your condition and whether you are taking any other medicines.

The usual dosage is:

Adults: 1-15 mg per day depending on severity, up to 100 mg per day.

Elderly: 1-3 mg per day is usually sufficient.

Children: Initial dose: 1-3 mg per day. Maintenance dose: 0.05 mg per kg of body weight daily.

How to take it

Tablets:

Swallow SERENACE tablets with a glass of water.

Oral liquid:

Shake the bottle well and accurately measure the dose with a medicine measure.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

How long to take it for

Continue taking the tablets or liquid for as long as your doctor tells you.

SERENACE helps control your condition but does not cure it. Therefore, it is important that you keep taking it every day.

Do not stop taking SERENACE unless your doctor tells you to, even if you feel better.

When to take it

Take SERENACE 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.

It does not matter if you take SERENACE before or after food.

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 your medicine as you would normally.

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

If you take too much

If you think that you have taken too much SERENACE, 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.

5. What should I know while using SERENACE?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking SERENACE.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking SERENACE.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking SERENACE.

If you need to have any medical tests while you are taking SERENACE, tell your doctor.

It may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some blood/eye/skin tests from time to time. This helps to prevent unwanted side effects.

If SERENACE makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

If outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sun lamp or tanning bed or booth.

SERENACE may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn.

Make sure you keep cool in hot weather and keep warm in cool weather.

SERENACE may affect the way your body reacts to temperature changes.

Call your doctor straight away if:

- **you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw, which may progress to the arms and legs.**
These are symptoms of a condition called Tardive dyskinesia, which may develop in people taking antipsychotic medicines, including SERENACE. This condition is more likely to occur during long term treatment with this medicine, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.
- **you become pregnant while taking SERENACE**
- **your skin appears to be burning after sun or UV exposure.**

Things you should not do

Do not give SERENACE to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take SERENACE to treat any other complaints unless your doctor tells you to.

Do not stop taking SERENACE, or lower the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking SERENACE suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually

reduce the amount of SERENACE you take each day before stopping the medicine completely.

Do not take any medicines that cause drowsiness while you are taking SERENACE, unless recommended by your doctor.

Driving or using machines

Be careful driving or operating machinery until you know how SERENACE affects you.

As with other antipsychotic medicines, SERENACE may cause dizziness, light-headedness, tiredness, and drowsiness in some people. Make sure you know how you react to SERENACE before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or lightheaded.

Drinking alcohol

Be careful when drinking alcohol while taking SERENACE. Combining SERENACE and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are taking SERENACE.

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep SERENACE in the original packaging, in a cool dry place, away from light where the temperature stays below 30°C.

For example, do not store it:

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

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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.

6. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are taking SERENACE.

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 following information 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"> • drowsiness or tiredness • restlessness, agitation, anxiety or excitement • confusion • headaches • inability to sleep • muscle weakness • difficulty in speaking and/or swallowing • increased or decreased sweating • dry mouth • indigestion • nausea and/or vomiting • increased or loss of appetite • weight changes • constipation • diarrhoea • increased salivation • blurred vision or difficulty focusing • changes in skin colour (pale skin) • hot, dry skin • swelling of your hands, feet and/or ankles • painful, swollen breasts or breast enlargement in men • unusual secretion of breast milk • changes in your menstrual periods • impaired sexual function in men • loss of blood sugar control, including in diabetes. 	<p>Speak to your doctor or pharmacist if you have any of these common side effects and they worry you.</p> <p>These side effects are usually mild and short lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash • pinkish, itchy swellings on the skin, also called hives or nettle rash • red, itchy spots which may blister or form raised, red, pale-centered marks • extremely high body temperature (fever) • symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occur more quickly than normal • dizziness or spinning sensation (vertigo) • unable to pass urine • fast breathing • fast, pounding or irregular heart beats • signs of frequent infections such as fever, chills, sore throat or mouth ulcers • asthma and other breathing difficulties 	<p>Call your doctor straight away if you notice any of these serious side effects.</p> <p>You may need medical attention. Serious side effects are rare.</p>

<ul style="list-style-type: none"> • bleeding or bruising more easily than normal • tiredness, headaches, being short of breath when exercising, dizziness and looking pale (anaemia) • yellowing of the skin and/or eyes • unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs • sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body • persistent painful erection (priapism) • seeing, feeling or hearing things that are not there (hallucinations) • worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs • regular episodes of irregular heartbeat, dizziness and loss of consciousness. 	
<ul style="list-style-type: none"> • sudden signs of allergy such as skin rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing • severe spasms in the muscles of the shoulders, neck and upper body • convulsions, fits or seizures • sudden increase in body temperature, with sweating, fast heartbeat, muscle stiffness and fluctuating blood pressure which may lead to coma (neuroleptic malignant syndrome) • collapse. 	<p>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>You may need urgent medical attention or hospitalization. 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.

You may notice some side effects after you have finished taking SERENACE as the effects may last for days after you have stopped taking it.

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 SERENACE tablets contain

Active ingredient (main ingredient)	Each tablet contains either haloperidol 0.5 mg, 1.5 mg or 5 mg.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • acacia • calcium hydrogen phosphate dihydrate • lactose monohydrate • maize starch • magnesium stearate. <p>In addition, SERENACE 0.5 mg tablets only:</p> <ul style="list-style-type: none"> • quinolone yellow • green S. <p>SERENACE 5mg tablets only:</p> <ul style="list-style-type: none"> • brilliant scarlet 4R.
Potential allergens	Sugars as lactose.

What SERENACE LIQUID oral liquid contains

Active ingredient (main ingredient)	Each 1 mL contains haloperidol 2 mg.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactic acid • methyl hydroxybenzoate • propyl hydroxybenzoate • purified water.
Potential allergens	• hydroxybenzoates.

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

What SERENACE looks like

Tablets:

- SERENACE 0.5 mg are round green uncoated tablets, scored on one side and plain on the other side. Available in HDPE bottles of 100 tablets.
- SERENACE 1.5 mg are round white uncoated tablets, scored on one side and plain on the other side. Available in HDPE bottles of 100 tablets.

- SERENACE 5 mg are round red uncoated tablets, scored on one side and plain on the other side. Available in HDPE bottles of 50 tablets.

Oral liquid:

- SERENACE LIQUID 2 mg/mL is a clear, colourless oral liquid in 100 mL glass bottles.

Australian Registration numbers:

- SERENACE 0.5 mg tablet: AUST R 10259
- SERENACE 1.5 mg tablet: AUST R 10258
- SERENACE 5 mg tablet: AUST R 10262
- SERENACE LIQUID 2 mg/mL oral liquid: AUST R 10257

Who distributes SERENACE

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

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