

SERENACE [Tablets and 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. SERENACE is used to treat mental illness including schizophrenia, mania, severe anxiety, behaviour problems in children with mental retardation, nausea and vomiting caused by cancer treatment, Tourette's syndrome and anxiety and pain during surgery.

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 SERENACE 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?

- Tablets: Swallow SERENACE tablets with a glass of water.
- Liquid: Shake the bottle well and accurately measure the dose with a medicine measure.
- Take SERENACE at about the same time each day.

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.• Tell your doctor 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.• If you plan to have surgery that needs a general anesthetic, tell your doctor or dentist that you are taking SERENACE.• 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 SPF 15+ sunscreen.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage, even if you are feeling better, without checking with your doctor.• Do not take any medicines that cause drowsiness while you are taking SERENACE, unless recommended by 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.• It may cause dizziness, light-headedness, tiredness and drowsiness in some people. If this occurs, do NOT drive.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking SERENACE.• It may make you more sleepy, dizzy or light-headed.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets or liquid in their container until it is time to take them.• Keep your tablets or liquid in a cool dry place 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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SERENACE. Some mild side effects include drowsiness, restlessness, agitation, anxiety, confusion, muscle weakness, nausea and vomiting. Some more serious side effects include skin rash, hives, extremely high body temperature, dizziness, unable to pass urine and breathing difficulties.

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

SERENACE [Tablets and Liquid]

Active ingredient(s): 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 [medicine name].**

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. SERENACE is an antipsychotic that works 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.

SERENACE is used to treat:

- 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
- 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).

Your doctor may have prescribed SERENACE for another reason.

2. What should I know before I use SERENACE?

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.

There is no evidence that this medicine is addictive or habit forming.

Warnings

Do not use SERENACE if:

- You are allergic to haloperidol, 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 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
 - serious heart condition e.g. heart attack, heart failure, unusual heartbeat
- You are taking medicines used to treat fast or irregular heartbeat (arrhythmia)
- If the individual is unconscious or in a coma.
- It is after the expiry date (EXP) printed on the pack.
- If the packaging is torn or shows signs of tampering.

Symptoms of an allergic reaction to SERENACE may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives.

Check with your doctor if you:

Take any medicines for any other condition.

If you smoke as:

- Nicotine can affect the amount of haloperidol in your body. Sudden change in your usual smoking habits can also change the effects of haloperidol.

Will be in a hot environment or do a lot of exercise as:

- SERENACE may make you sweat less, causing your body to overheat.

Have any other medical conditions, especially:

- 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)
- Unusual amount of salt in the body
- 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 or underactive 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
- Subarachnoid haemorrhage, serious bleeding around the brain
- Alcoholism or drug dependence
- Dementia-related psychosis, loss of memory or mental ability.

The elderly with dementia-related psychosis and taking SERENACE may have a rare increased risk of death. Talk to your doctor if you have any questions.

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.

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.

Babies exposed to antipsychotic medicines including SERENACE during the third trimester of pregnancy are at risk of experiencing breathing problems, difficulty in feeding, spasms, restlessness, involuntary movements and/or withdrawal symptoms following delivery.

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

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

Use in Children

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.

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

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 and SERENACE may interfere with each other. 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 hayfever, 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 heartbeat (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

The above medicines may either reduce the effectiveness of SERENACE, reduce its own effectiveness, and/or react with SERENACE resulting in untoward or sometimes dangerous side effects.

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 / use

- Follow the instructions provided and use SERENACE until your doctor tells you to stop.
- Your doctor or pharmacist will tell you how much SERENACE you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

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

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

Children:

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

When to take / use SERENACE

- Take SERENACE at about the same time each day.
- Take 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.

How to use

- Tablets: Swallow SERENACE tablets with a glass of water.
- 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

- 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.

If you forget to use SERENACE

SERENACE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then return to taking your medicine as you would normally.

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

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 use too much SERENACE (overdose)

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

Symptoms of an overdose to SERENACE include some of the side effects listed under Section [6. Are there any side effects?](#), but are usually of a more severe nature. If you are given too much SERENACE you may have coma, breathing difficulty, low or high blood pressure, drowsiness, muscle weakness or stiffness, unusual heartbeat, unusual or uncontrollable movements such as shaking and trembling.

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.

Tell your doctor if you become pregnant while 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.

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.

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

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.

Dizziness

- If SERENACE makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.
- Getting up slowly may help. This will allow your body to get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Sun Sensitivity

- If outdoors, wear protective clothing and use at least a SPF 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. If your skin does appear to be burning, tell your doctor immediately.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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 light-headed.

If this occurs, do NOT drive.

Drinking alcohol

Tell your doctor if you drink 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.

Looking after your medicine

- Keep your tablets or liquid in their container until it is time to take them.
- If you take the tablets or the liquid out of the container, they may not keep well.
- Keep your tablets or liquid 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 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.

Young children or adolescents and the elderly may have an increased chance of getting 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 appetite• loss of appetite• weight changes• constipation• diarrhoea• increased salivation• blurred vision or difficulty focusing	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>These are the more common side effects of SERENACE. They are usually mild and short-lived.</p>

<ul style="list-style-type: none"> • 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 	
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<ul style="list-style-type: none"> • 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. 	
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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-centred 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 • 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) 	<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>You may need urgent medical attention. Serious side effects are rare.</p>

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

<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 heart beat, muscle stiffness and fluctuating blood pressure which may lead to coma (neuroleptic malignant syndrome) • very fast, uneven or forceful heartbeat (palpitations), weakness, fainting (symptoms relating to QT prolongation and Torsade de Pointes) • collapse 	
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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. The effects of SERENACE 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 contains

Active ingredient (main ingredient)	SERENACE tablets contain: Haloperidol 0.5 mg, 1.5 mg and 5 mg SERENACE Liquid contains: Haloperidol 2 mg/mL
Other ingredients (inactive ingredients)	SERENACE tablets contain: <ul style="list-style-type: none">• lactose• starch – maize• acacia• magnesium stearate• calcium hydrogen phosphate SERENACE 0.5 mg tablets also contain: <ul style="list-style-type: none">• quinoline yellow CI47005• green s CI44090 SERENACE 5 mg tablets also contain: <ul style="list-style-type: none">• brilliant scarlet 4R CI16255 SERENACE Liquid contains: <ul style="list-style-type: none">• lactic acid• methyl hydroxybenzoate (preservative)• propyl hydroxybenzoate (preservative)• water
Potential allergens	Lactose

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

SERENACE products do not contain any sucrose, gluten, or tartrazine.

What SERENACE looks like

SERENACE Tablets: (oral)

0.5 mg tablet is green, scored, uncoated, plain on one side, in bottles of 100. (AUST R 10259).

1.5 mg tablet is white, scored, uncoated, plain on one side, in bottles of 100. (AUST R 10258).

5 mg tablet is red, scored, uncoated, plain on one side, in bottles of 50 and 100. (AUST R 10262).

SERENACE Liquid: (oral)

2 mg per mL liquid is a clear, colourless liquid in 100 mL bottles. (AUST R 10257).

Who distributes SERENACE

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

This leaflet was prepared in October 2022.