

SERENACE injection

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 an antipsychotic used to treat schizophrenia, mania, severe anxiety, behavioral problems in children and Tourette's syndrome.

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 decide what dose you will receive. This depends on your condition and other factors such as your weight.
- SERENACE is given as an injection into a muscle or a slow injection into a vein, by a health care professional.

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 immediately if you notice 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 using 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 take any medicines that cause drowsiness while you are using SERENACE, unless recommended by your doctor.• Do not use a sunlamp or tanning bed or booth.
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 using SERENACE. It may make you more sleepy, dizzy or lightheaded.
Looking after your medicine	<ul style="list-style-type: none">• It should be stored in a cool dry place, protected 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?

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

Some mild side effects include redness and pain at the injection site, drowsiness or tiredness, confusion, muscle weakness and restlessness. Some more serious side effects include skin rash, hives, extremely high body temperature, sunburn symptoms, dizziness, yellowing of skin and unusual movements including shaking and twisting movements of the body.

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.

SERENACE injection

Active ingredient: *haloperidol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using SERENACE injection.

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. SERENACE is an antipsychotic which helps to correct chemical imbalances in the brain.

SERENACE is used to 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
- 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).

Ask your doctor if you have any questions about why this medicine has been given to you.

Your doctor may have prescribed it 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.

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 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.
- **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)**
- **the individual is unconscious or in a coma**
- **it is after the expiry date printed on the pack.**
- **the packaging is torn or shows signs of tampering.**

Check with your doctor, nurse or pharmacist if you:

- **take any other medicines.**
- **smoke.** 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 heart beats (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
- serious starvation (lack of food)
- alcoholism or drug dependence
- dementia-related psychosis (loss of memory and other 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 use while breastfeeding 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 side 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.

Check with your doctor, nurse 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 is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors such as your weight.

How it is given

Except under unusual circumstances, SERENACE is given as an injection into a muscle or as a slow injection into a vein, by a health care professional.

How long is it given for

SERENACE injection should be administered as recommended by your doctor.

If you are given too much SERENACE injection

As SERENACE injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Tell your doctor or nurse immediately if you experience any side effects after being given SERENACE injection.

If any overdose occurs, 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 overdose include some of the side effects listed under Section 6. [Are there any side effects?](#) and may include coma, breathing difficulty, low or high blood pressure, drowsiness, muscle weakness or stiffness, unusual heartbeat, unusual or uncontrollable movements such as shaking and trembling.

5. What should I know while using SERENACE?

Things you should do

Tell your doctor or nurse if:

- you have any questions about why this medicine has been given to you.
- you are using SERENACE and you plan to have surgery that needs a general anaesthetic.
- you become pregnant while using SERENACE.
- you need to have any medical tests while you are taking SERENACE. 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 may want to take some blood or request eye or skin tests to check your progress from time to time. This helps 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.

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 and temperature 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.

Combining SERENACE and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with SERENACE.

Looking after this medicine

SERENACE injection should be kept in a cool dry place, protected from light where the temperature stays below 30°C

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"> • redness and pain at the injection site • 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 • 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 nurse 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>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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) • sunburn (such as redness, itching, swelling or blistering of the skin) 	<p>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

<p>which occur more quickly than normal</p> <ul style="list-style-type: none"> • dizziness or spinning sensation • 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 • 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 arms and legs • sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body • in men, persistent painful erection • seeing, feeling or hearing things that are not there • 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. 	<p>these serious side effects.</p> <p>Serious side effects are rare.</p>
<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) • very fast, uneven or forceful heartbeat (palpitations), weakness, fainting • collapse. 	<p>You may need urgent medical attention or hospitalisation.</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.

You may notice some side effects after you have finished using SERENACE. The effects of it may last for days after you have stopped use.

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.

7. Product details

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

What SERENACE contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Each 1 mL ampoule contains haloperidol 5 mg.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• (S)-lactic acid• sodium hydroxide• water for injections.

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

What SERENACE looks like

SERENACE injection is a clear, colourless liquid practically free of visible particles. Available in an amber coloured 1 mL glass ampoule in packs of 10 ampoules.

Australian Registration number: AUST R 188367.

Who distributes SERENACE

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

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