

SERENACE tablets and liquid

haloperidol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SERENACE. It does not contain all 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 SERENACE 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 SERENACE is used for

SERENACE 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.

Your doctor may have prescribed SERENACE for another reason.

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

SERENACE belongs to a group of medicines called antipsychotics. It 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.*

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

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

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.

Before using it

When you must not use it

Do not take SERENACE if you have an allergy to:

- haloperidol
- 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

Do not take SERENACE if 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

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

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 3 years of age.

Do not take it after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking SERENACE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you are allergic to:

- any other medicines
- any other substances, such as foods, dyes or preservatives

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 breast-feeding or plan to breast-feed.

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

Tell your doctor if 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 heart beats (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

Tell your doctor if 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.

Tell your doctor if you 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking SERENACE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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 heart beats (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.

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking SERENACE.

How much to take

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

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.

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.

How to take it

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.

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 that you missed.

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

If you are not sure what to do, ask your doctor or pharmacist.

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

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 take too much (overdose)

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

has been taken. You may need urgent medical attention.

Keep telephone numbers for these places handy.

Symptoms of an overdose of SERENACE may include some of the side effects listed below (see "Side Effects" section), but are usually of a more severe nature.

While you are using it

Things you must do

Tell your doctor immediately 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.

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.

Things you must 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.

Things to be careful of

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 light-headed. If this occurs, do NOT drive.

If this occurs, do NOT drive.

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.

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.

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. 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.

Side effects

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

SERENACE helps most people with the conditions listed at the beginning of this leaflet, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Young children or adolescents and the elderly may have an increased chance of getting side effects.

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

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

- 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 focussing
- 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

These are the more common side effects of SERENACE. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- 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)
- 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.

These may be serious side effects. You may need urgent medical

attention. Serious side effects are rare.

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

- 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)
- collapse

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell, while taking SERENACE.

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.

After taking it

Storage

Keep your tablets or liquid in their bottle until it is time to take them.

If you take the tablets or the liquid out of the pack, they may not keep well.

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

Do not store SERENACE or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on windowsills.

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 SERENACE or the medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

SERENACE Tablets: (oral)

0.5 mg, green, scored, uncoated, plain on one side, in bottles of 100

1.5 mg, white, scored, uncoated, plain on one side, in bottles of 100.

5 mg, red, scored, uncoated, plain on one side, in bottles of 50 and 100.

SERENACE Liquid: (oral)

2 mg per mL clear, colourless liquid in 100 mL bottles.

Ingredients

Active Ingredient:

- Haloperidol 0.5 mg, 1.5 mg and 5 mg Tablets and 2 mg/mL Liquid.

Other Ingredients:

SERENACE tablets contain:

- lactose
- starch – maize
- acacia
- magnesium stearate

- calcium hydrogen phosphate

SERENACE 0.5 mg tablets also contain:

- quinoline yellow CI47005
- green s CI44090

SERENACE 5 mg tablets also contain:

- brilliant scarlet 4R CI16255

SERENACE Liquid contains:

- lactic acid
- methyl hydroxybenzoate (preservative)
- propyl hydroxybenzoate (preservative)
- water

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

The Australian Product Registration Numbers for:

SERENACE Tablets 0.5 mg:
AUST R 10259

SERENACE Tablets 1.5 mg:
AUST R 10258

SERENACE Tablets 5 mg:
AUST R 10262

SERENACE 2 mg/mL Liquid is
AUST R 10257.

Sponsor

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

This leaflet was revised in January 2020.