

Serenace 500 micrograms Capsules
haloperidol

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Serenace is and what it is used for**
- 2. What you need to know before you take Serenace**
- 3. How to take Serenace**
- 4. Possible side effects**
- 5. How to store Serenace**
- 6. Contents of the pack and other information**

1. What Serenace is and what it is used for

The name of your medicine is Serenace.

Serenace contains the active substance haloperidol. This belongs to a group of medicines called 'antipsychotics'.

Serenace is used in adults, adolescents and children for illnesses affecting the way you think, feel or behave. These include mental health problems (such as schizophrenia and bipolar disorder) and behavioural problems.

These illnesses may make you:

- Feel confused (delirium)
- See, hear, feel or smell things that are not there (hallucinations)
- Believe things that are not true (delusions)
- Feel unusually suspicious (paranoia)
- Feel very excited, agitated, enthusiastic, impulsive or hyperactive
- Feel very aggressive, hostile or violent.

In adolescents and children, Serenace is used to treat schizophrenia in patients aged 13 to 17 years, and to treat behavioural problems in patients aged 6 to 17 years.

Serenace is also used:

- In adolescents and children aged 10 to 17 years and in adults for movements or sounds you can't control (tics), for example in severe Tourette's syndrome
- In adults to help control movements in Huntington's disease.

Serenace is sometimes used when other medicines or treatments have not worked or caused unacceptable side effects.

2. What you need to know before you take Serenace

DO NOT take Serenace if:

- You are allergic (hypersensitive) to haloperidol or any of the other ingredients of this medicine (listed in section 6)
- You are less aware of things around you or your reactions become unusually slow
- You have Parkinson's disease
- You have a type of dementia called 'Lewy body dementia'
- You have progressive supranuclear palsy (PSP)
- You have a heart condition called 'prolonged QT interval', or any other problem with your heart rhythm that shows as an abnormal tracing on an ECG (electrocardiogram)
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- You have heart failure or recently had a heart attack You have a low level of potassium in your blood, which has not been treated
- You take any of the medicines listed under 'Other medicines and Serenace – Do not take Serenace if you are taking certain medicines for'.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Serenace.

Warnings and precautions

Serious side effects

Serenace can cause problems with the heart, problems controlling body or limb movements and a serious side effect called 'neuroleptic malignant syndrome'. It can also cause severe allergic reactions and blood clots. You must be aware of serious side effects while you are taking Serenace because you may need urgent medical treatment. See 'Look out for serious side effects' in section 4.

Elderly people and people with dementia

A small increase in deaths and strokes has been reported for elderly people with dementia who are taking antipsychotic medicines. Talk to your doctor or pharmacist before taking Serenace if you are elderly, particularly if you have dementia.

Talk to your doctor or pharmacist if you have:

- A slow heart beat, heart disease or anyone in your close family has died suddenly of heart problems
- Low blood pressure, or feel dizzy upon sitting up or standing up
- A low level of potassium or magnesium (or other 'electrolyte') in your blood. Your doctor will decide how to treat this
- Ever had bleeding in the brain, or your doctor has told you that you are more likely than other people to have a stroke
- Epilepsy or have ever had fits (convulsions)
- Problems with your kidneys, liver or thyroid gland
- A high level of the hormone 'prolactin' in your blood, or cancer that may be caused by high prolactin levels (such as breast cancer)
- A history of blood clots, or someone else in your family has a history of blood clots
- Depression, or you have bipolar disorder and start to feel depressed.

You may need to be more closely monitored, and the amount of Serenace you take may have to be altered.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Serenace.

Medical check ups

Your doctor may want to take an electrocardiogram (ECG) before or during your treatment with Serenace. The ECG measures the electrical activity of your heart.

Blood tests

Your doctor may want to check the levels of potassium or magnesium (or other 'electrolyte') in your blood before or during your treatment with Serenace.

Children below 6 years of age

Serenace should not be used in children below 6 years of age. This is because it has not been studied adequately in this age group.

Other medicines and Serenace

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

DO NOT take Serenace if you are taking certain medicines for:

- Problems with your heart beat (such as amiodarone, dofetilide, disopyramide, dronedarone, ibutilide, quinidine and sotalol)
- Depression (such as citalopram and escitalopram)
- Psychoses (such as fluphenazine, levomepromazine, perphenazine, pimozide, prochlorperazine, promazine, sertindole, thiorizadine, trifluoperazine, triflupromazine and ziprasidone)
- Bacterial infections (such as azithromycin, clarithromycin, erythromycin, levofloxacin, moxifloxacin and telithromycin)
- Fungal infections (such as pentamidine)
- Malaria (such as halofantrine)
- Nausea and vomiting (such as dolasetron)
- Cancer (such as toremifene and vandetanib).

Also tell your doctor if you are taking bepridil (for chest pain or to lower blood pressure) or methadone (a pain killer or to treat drug addiction). These medicines may make heart problems more likely, so talk to your doctor if you are taking any of these and do not take Serenace (see 'Do not take Serenace if').

Special monitoring may be needed if you are taking lithium and Serenace at the same time. Tell your doctor straight away and stop taking both medicines if you get:

- Fever you can't explain or movements you can't control
- Confused, disoriented, a headache, balance problems and feel sleepy.

These are signs of a serious condition.

Certain medicines may affect the way that Serenace works or may make heart problems more likely

Tell your doctor if you are taking:

- Alprazolam or buspirone (for anxiety)
- Duloxetine, fluoxetine, fluvoxamine, nefazodone, paroxetine, sertraline, St John's Wort (*Hypericum perforatum*) or venlafaxine (for depression)
- Bupropion (for depression or to help you stop smoking)
- Carbamazepine, phenobarbital or phenytoin (for epilepsy)
- Rifampicin (for bacterial infections)
- Itraconazole, posaconazole or voriconazole (for fungal infections)
- Ketoconazole tablets (to treat Cushing's syndrome)
- Indinavir, ritonavir or saquinavir (for human immunodeficiency virus or HIV)

- Chlorpromazine or promethazine (for nausea and vomiting)
- Verapamil (for blood pressure or heart problems).

Also tell your doctor if you are taking any other medicines to lower blood pressure, such as water tablets (diuretics).

Your doctor may have to change your dose of Serenace if you are taking any of these medicines.

Serenace can affect the way the following types of medicine work

Tell your doctor if you are taking medicines for:

- Calming you down or helping you to sleep (tranquillisers)
- Pain (strong pain killers)
- Depression ('tricyclic antidepressants')
- Lowering blood pressure (such as guanethidine and methyldopa)
- Severe allergic reactions (adrenaline)
- Attention deficit hyperactivity disorder (ADHD) or narcolepsy (known as 'stimulants')
- Parkinson's disease (such as levodopa)
- Thinning the blood (phenindione).

Talk to your doctor before taking Serenace if you are taking any of these medicines.

Serenace and alcohol

Drinking alcohol while you are taking Serenace might make you feel sleepy and less alert. This means you should be careful how much alcohol you drink. Talk to your doctor about drinking alcohol while taking Serenace, and let your doctor know how much you drink.

Pregnancy and breast-feeding

Pregnancy - if you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice. Your doctor may advise you not to take Serenace while you are pregnant.

The following problems may occur in newborn babies of mothers that take Serenace in the last 3 months of their pregnancy (the last trimester):

- Muscle tremors, stiff or weak muscles
- Being sleepy or agitated
- Problems breathing or feeding.

The exact frequency of these problems is unknown. If you took Serenace while pregnant and your baby develops any of these side effects, contact your doctor.

Breast-feeding – talk to your doctor if you are breast-feeding or planning to breast-feed. This is because small amounts of the medicine may pass into the mother's milk and on to the baby. Your doctor will discuss the risks and benefits of breast-feeding while you are taking Serenace.

Fertility – Serenace may increase your levels of a hormone called 'prolactin', which may affect fertility in men and women. Talk to your doctor if you have any questions about this.

Driving and using machines

Serenace can affect your ability to drive and use tools or machines. Side effects, such as feeling sleepy, may affect your alertness, particularly when you first start taking it or after a high dose. Do not drive or use any tools or machines without discussing this with your doctor first.

Serenace contains lactose and tartrazine (E102)

Serenace contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Serenace also contains **tartrazine (E102)** which may cause allergic reactions.

3. How to take Serenace

Always take Serenace exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How much should you take

Your doctor will tell you how many tablets to take and for how long. Your doctor will also tell you whether to take Serenace one or more times a day. It may be some time before you feel the full effect of the medicine. Your doctor will normally give you a low dose to start, and then adjust the dose to suit you. It is very important you take the correct amount.

Your dose of haloperidol will depend on:

- Your age
- What condition you are being treated for
- Whether you have problems with your kidneys or liver
- Other medicines you are taking.

Adults

- Your dose will normally be between 0.5 mg and 10 mg each day.
- Your doctor may adjust this to find the dose that suits you best.
- The highest dose adults should take depends on the condition you are being treated for and varies between 5 mg and 20 mg each day.

Elderly people

- Elderly people will normally start on 0.5 mg each day or half the lowest adult dose.
- The number of tablets you take will then be adjusted until the doctor finds the dose that suits you best.
- The highest dose elderly people should take is 5 mg each day unless your doctor decides a higher dose is needed.

Children and adolescents 6 to 17 years of age

- Your dose will normally be between 0.5 mg and 3 mg each day.
- Adolescents up to 17 years of age being treated for schizophrenia or behavioural problems may have a higher dose, up to 5 mg each day.

Taking Serenace

- Serenace is for oral use.
- Swallow the tablets with some water.

If you take more Serenace than you should

If you take more Serenace than you were told to or if someone else has taken any Serenace, talk to a doctor or go to the nearest hospital casualty department straight away.

If you forget to take Serenace

- If you forget to take a dose, take your next dose as usual. Then keep taking your medicine as your doctor has told you.
- Do not take a double dose.

If you stop taking Serenace

Unless your doctor tells you otherwise, you should stop taking Haldol gradually. Stopping treatment suddenly may cause effects such as:

- Nausea and vomiting
- Difficulty sleeping.

Always follow your doctor's instructions carefully.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Look out for serious side effects

Tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

Problems with the heart:

- Abnormal heart rhythm – this stops the heart working normally and may cause loss of consciousness
- Abnormally fast heart beat
- Extra heart beats.

Heart problems are uncommon in people taking Serenace (may affect up to 1 in 100 people). Sudden deaths have occurred in patients taking this medicine, but the exact frequency of these deaths is unknown. Cardiac arrest (the heart stops beating) has also occurred in people taking antipsychotic medicines.

A serious problem called ‘neuroleptic malignant syndrome’. This causes a high fever, severe muscle stiffness, confusion and loss of consciousness. It is rare in people taking Serenace (may affect up to 1 in 1,000 people).

Problems controlling movements of the body or limbs (extrapyramidal disorder), such as:

- Movements of the mouth, tongue, jaw and sometimes limbs (tardive dyskinesia)
- Feeling restless or difficulty sitting still, increased body movements
- Slow or reduced body movements, jerking or twisting movements
- Muscle tremors or stiffness, a shuffling walk
- Being unable to move
- Lack of normal facial expression that sometimes looks like a mask.

These are very common in people taking Serenace (may affect more than 1 in 10 people). If you get any of these effects, you may be given an additional medicine.

Severe allergic reaction that may include:

- A swollen face, lips, mouth, tongue or throat
- Difficulty swallowing or breathing
- Itchy rash (hives).

An allergic reaction is uncommon in people taking Serenace (may affect up to 1 in 100 people).

Blood clots in the veins, usually in the legs (deep vein thrombosis or DVT). These have been reported in people taking antipsychotic medicines. The signs of a DVT in the leg include swelling, pain and redness in the leg, but the clot may move to the lungs causing chest pain and difficulty in breathing. Blood clots can be very serious, so tell your doctor straight away if you notice any of these problems.

Tell your doctor straight away if you notice any of the serious side effects above.

Other side effects

Tell your doctor if you notice or suspect any of the following side effects.

Very common (may affect more than 1 in 10 people):

- Feeling agitated
- Difficulty sleeping

- Headache.

Common (may affect up to 1 in 10 people):

- Serious mental health problem, such as believing things that are not true (delusions) or seeing, feeling, hearing or smelling things that are not there (hallucinations)
- Depression
- Abnormal muscle tension
- Feeling dizzy, including upon sitting up or standing up
- Feeling sleepy
- Upward movement of the eyes or fast eye movements that you cannot control
- Problems with vision, such as blurred vision
- Low blood pressure
- Nausea, vomiting
- Constipation
- Dry mouth or increased saliva
- Skin rash
- Being unable to pass urine or empty the bladder completely
- Difficulty getting and keeping an erection (impotence)
- Weight gain or loss
- Changes that show up in blood tests of the liver.

Uncommon (may affect up to 1 in 100 people):

- Effects on blood cells – low number of all types of blood cells, including severe decreases in white blood cells and low number of ‘platelets’ (cells that help blood to clot)
- Feeling confused
- Loss of sex drive or decreased sex drive
- Fits (seizures)
- Stiff muscles and joints
- Muscle spasms, twitching or contractions that you cannot control, including a spasm in the neck causing the head to twist to one side
- Problems walking
- Being short of breath
- Inflamed liver, or liver problem that causes yellowing of the skin or eyes (jaundice)
- Increased sensitivity of the skin to sunlight
- Itching
- Excessive sweating
- Changes in menstrual cycle (periods), such as no periods, or long, heavy, painful periods
- Unexpected production of breast milk
- Breast pain or discomfort
- High body temperature
- Swelling caused by fluid build-up in the body.

Rare (may affect up to 1 in 1,000 people):

- High level of the hormone ‘prolactin’ in the blood
- Narrowed airways in the lungs, causing difficulty breathing
- Difficulty or being unable to open the mouth
- Problems having sex.

The following side effects have also been reported, but their exact frequency is unknown:

- High level of ‘antidiuretic hormone’ in the blood (syndrome of inappropriate antidiuretic hormone secretion)
- Low level of sugar in the blood
- Swelling around the voice box or brief spasm of the vocal cords, which may cause difficulty speaking or breathing
- Sudden liver failure

- Decreased bile flow in the bile duct
- Flaking or peeling skin
- Inflamed small blood vessels, leading to a skin rash with small red or purple bumps
- Breakdown of muscle tissue (rhabdomyolysis)
- Persistent and painful erection of the penis
- Enlarged breasts in men
- Low body temperature.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Serenace

Keep out of the sight and reach of children.

Do not store above 30°C. Store in the original container (bottles) or package (blisters).

Do not use Serenace after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Serenace contains

The active ingredient is haloperidol 500 micrograms.

The other ingredients are lactose monohydrate and maize starch. The capsule shell contains gelatin, titanium dioxide (E171), tartrazine (E102), and Patent Blue V (E131).

What Serenace looks like and contents of the pack

Serenace Capsules are two-tone green, hard gelatin capsules, printed 'Norton 500' on one half and 'SERENACE' on the other.

The capsules are available in bottles of 50, 250 and 1000 or blister packs of 30 and 100.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

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