

# SERDOLECT®

Serdolect® Tablets 4, 12, 16 and 20 mg

Sertindole

## Consumer Medicine Information

### What is in this leaflet

This leaflet contains answers to some common questions about Serdolect.

It does not contain all the information that is known about Serdolect. 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 Serdolect against the benefits he/she expects 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 Serdolect is used for

Serdolect is used to treat schizophrenia, a mental illness with disturbances in thinking, emotional reactions and behaviour.

Serdolect belongs to a group of medicines called antipsychotics. It helps to correct certain chemical imbalances in the brain which cause the symptoms of your illness.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.** Your doctor may have prescribed it for another reason.

Serdolect is not addictive.

There is not enough information to recommend the use of this medicine for children and adolescents under the age of 18 years.

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

### Before you take Serdolect

#### When you must not take it

**Do not take Serdolect if you have an allergy to:**

- any medicine containing sertindole.
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines.

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

**Do not take Serdolect if you have, or ever have had, any of the following medical conditions:**

- Disturbed water or salt balance (low potassium or low magnesium levels in the blood) which is currently not being treated by your doctor
- Severe blood vessel disease or severe heart disease such as heart failure, cardiac hypertrophy (thickening of the heart muscles), arrhythmia (changes in the way the heart beats), or slow heart beat (less than 50 beats per minute)
- Severe liver problems

**Also do not take Sertindole if your doctor has recorded an electrocardiogram (ECG, a record of the electrical activity of your heart) and has identified a prolongation of the QT interval (a certain part of an ECG). Such a condition may be hereditary or may develop spontaneously.**

**Do not take Serdolect at the same time as medicines that may**

**prolong the QT interval or may affect the amount of Serdolect in your blood, such as:**

- Antiarrhythmic medicines, used to treat irregular heart beats, e.g. quinidine, amiodarone, sotalol, dofetilide
- Antipsychotic medicines, used to treat certain mental and emotional conditions, e.g. thioridazine
- Macrolide antibiotics, e.g. erythromycin, clarithromycin
- Quinolone antibiotics, e.g. gatifloxacin, moxifloxacin
- Antihistamine medicines, used to prevent or relieve the symptoms of allergy (such as hay fever), e.g. terfenadine, astemizole
- 'Azole' antifungal medicines, e.g. ketoconazole, itraconazole
- Calcium channel blocker medicines, used to treat high blood pressure and angina, e.g. diltiazem, verapamil
- Lithium, used to treat mood swings and some types of depressions
- Medicines used to treat stomach problems, e.g. cisapride, cimetidine
- Medicines used to treat HIV, e.g. indinavir

**Do not take this medicine after the expiry date printed on the pack or 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 Serdolect, talk to your doctor or pharmacist.**

#### Before you start to take it

Before and during treatment with Serdolect, your doctor will conduct certain examinations in order to

decide if treatment with Serdolect is safe for you. These examinations may include:

- an electrocardiogram (ECG) of your heart to check that the QT interval is not prolonged. This test will usually be repeated when you have been treated with Serdolect for approximately 3 weeks or when you reach a daily dose of 16 mg of Serdolect, and again after 3 months. It will then be repeated as often as your doctor decides and if your dose is increased or if the dose of other medicines you may be taking is changed.
- a blood sample to check the amount of magnesium and potassium in your blood. If the amount is too low, your doctor will need to treat this condition.
- monitoring your blood pressure.

#### **Tell your doctor if:**

- **you have allergies to any other medicines, foods, preservatives or dyes.**
- **have or have had any of the following medical conditions:**
  - Heart and blood vessel problems
  - Parkinsonism, a disease of the brain affecting movement
  - Liver problems
  - Tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs
  - Convulsions, fits or seizures
- **you are pregnant, or plan to become pregnant.**

The safety of Serdolect during pregnancy has not been established. Therefore, this medicine should not be used during pregnancy.
- **are breast-feeding or plan to breast-feed.**

Sertindole, the active ingredient in Serdolect, passes into breast milk and therefore there is a possibility that your baby may be affected. You should consider not breast-feeding while taking Sertindole. Your

doctor will be able to advise you.

#### **Also tell your doctor your age.**

If you are over 65 years of age, your doctor will examine you for any heart or blood vessel problems.

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

#### **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you get without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines and Serdolect may interfere with each other. These include:

- All medicines mentioned under *When you must not take it* at the beginning of this leaflet
- Dopamine agonists, used to treat Parkinson's disease
- Some SSRI medicines, e.g. fluoxetine and paroxetine, used to treat depression
- Medicines used to treat epilepsy, such as carbamazepine, phenytoin and phenobarbitone
- Rifampicin, an antibiotic most commonly used to treat tuberculosis

These medicines may be affected by Serdolect, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Serdolect.

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#### **How to take Serdolect**

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**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 box, ask your doctor or pharmacist for help.**

#### **How much to take**

##### *Initial phase*

The usual starting dose is 4 mg per day. Every 4 – 5 days, your doctor will increase the dose by 4 mg at a time, until a dose is reached where Serdolect works best for you.

##### *Long-term treatment (maintenance)*

Generally the dose is 12 – 20 mg of Serdolect once a day. Your doctor will determine the dose depending on your response to the medicine. Very rarely, he/she may need to prescribe the maximum dose of 24 mg per day.

##### *Elderly patients*

Your doctor will most likely increase your dose over a longer period of time than normally recommended. Possibly he/she will also prescribe a lower maintenance dose.

##### *Patients with liver problems*

Your doctor may want to monitor you more closely and will most likely increase your dose over a longer period of time than normally recommended. Possibly he/she will also prescribe a lower maintenance dose.

#### **How to take it**

Swallow the tablet whole with a full glass of water.

#### **When to take it**

Take Serdolect once a day at about the same time. This medicine can be taken with or without food.

#### **How long to take it**

**Continue taking your tablets as long as your doctor tells you.**

Serdolect helps control your condition, but the underlying illness may persist for a long time. If you stop your treatment too soon your symptoms may return. Therefore, It is important to keep taking your medicine even if you feel well.

### ***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, contact your doctor. He/she will make sure to restart your treatment the right way.

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

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

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

### ***If you take too much (overdose)***

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia and Tel: 0800 764 766 for New Zealand) 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 Serdolect. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include increased fatigue, slurred speech, increased pulse and lowering of the blood pressure.

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## **While you are taking Serdolect**

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### ***Things you must do***

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Serdolect.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking Serdolect, tell your doctor immediately.

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 similar medicines, including Serdolect.

This condition is more likely to occur during long-term treatment with Serdolect, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

Also tell your doctor if you experience palpitations (abnormal heart beat), if you faint or if you have a fit.

Your doctor may need to monitor you more closely during the treatment and may need to do an ECG test.

Tell your doctor if you experience vomiting or diarrhoea, or if you take diuretics (medicines used to treat high blood pressure and fluid build-up, also called water tablets).

Your doctor may measure the amount of potassium in your blood.

### ***Things you must not do***

Do not take Serdolect to treat any other complaint unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Your doctor will decide when and how to stop your treatment, to avoid unpleasant symptoms that might occur if it is stopped abruptly.

### ***Things to be careful of***

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

Generally this medicine does not make you sleepy, tired or drowsy, however it affects everyone differently. If you do feel sleepy, tired or drowsy, do not drive, operate machinery or do anything else that might be dangerous.

It is not recommended that Sertindole be taken with alcohol.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

This feeling will most likely go away when you have taken Serdolect for a while, however if it continues or gets worse, talk to your doctor.

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## **Side effects**

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

This medicine helps most people with schizophrenia, but it may have unwanted side effects in some people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting certain side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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:**

- Runny or blocked nose, sneezing, facial pressure or pain
- Dizziness or dizziness when standing up
- Dry mouth
- Weight gain
- Shortness of breath
- Swelling of hands, ankles or feet
- Tingling or numbness of the hands or feet, pins and needles
- Decreased ejaculatory volume
- Prolonged QT interval (ECG changes)
- More red and white blood cells in the urine

The above list includes the more common side effects of Serdolect.

**Tell your doctor immediately if you notice any of the following:**

- High blood sugar
- Fainting
- Fits or convulsions
- Irregular heart beat
- 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

The above list includes serious side effects that may require medical attention. Serious side effects are uncommon.

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

- Sudden increase in body temperature, extremely high blood pressure and severe convulsions
- Sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

### **After taking Serdolect**

#### **Storage**

**Keep Serdolect in the pack until it is time to take it.**

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

**Keep Serdolect in a cool dry place where the temperature stays below 25°C.**

**Keep Serdolect away from sunlight.**

**Do not store Serdolect or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep Serdolect 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

### **Serdolect description**

#### **What it looks like**

Serdolect 4 mg tablets are oval, yellow, biconvex film-coated tablets marked with "S4" on one side. It is available in blister packs of 20, 28, 30, 50, 98 or 100 tablets.

Serdolect 12 mg tablets are oval, beige, biconvex film-coated tablets marked with "S12" on one side. It is available in blister packs of 20, 28, 30, 50, 98 or 100 tablets.

Serdolect 16 mg tablets are oval, rose, biconvex film-coated tablets marked with "S16" on one side. It is available in blister packs of 20, 28, 30, 50, 98 or 100 tablets.

Serdolect 20 mg tablets are oval, pink, biconvex film-coated tablets marked with "S20" on one side. It is available in blister packs of 20, 28, 30, 50, 98 or 100 tablets.

#### **Ingredients**

##### **Active ingredient(s)**

Serdolect 4/12/16/20 mg tablets contain 4/12/16/20 mg sertindole as the active ingredient, respectively.

##### **Other ingredients**

Serdolect tablets also contain:

- Starch – maize
- Lactose
- Hydroxypropylcellulose
- Cellulose – microcrystalline
- Croscarmellose sodium
- Magnesium stearate
- Hypromellose
- Titanium dioxide
- Macrogol 400
- Iron oxide yellow (4/12/20 mg tablets only)
- Iron oxide red (12/16/20 mg tablets only)
- Iron oxide black CI (20 mg tablets only)

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

##### **Manufacturer/Distributor**

Serdolect is made by H. Lundbeck A/S, Denmark.

Distributed in New Zealand by:  
Healthcare Logistics  
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