

PACKAGE LEAFLET: INFORMATION FOR THE USER

Serdolect® 4 mg, 12 mg, 16 mg and 20 mg film-coated tablets
sertindole

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects are troubling, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT SERDOLECT IS AND WHAT IT IS USED FOR

How does Serdolect work?

Serdolect belongs to a group of medicines known as antipsychotics. These work by correcting imbalances in brain chemistry. Two of the naturally occurring chemical 'messengers' in the brain are called dopamine and serotonin. Too much dopamine and too little serotonin can produce symptoms of mental illness. The main ingredient of Serdolect is sertindole, which corrects the imbalance.

What is Serdolect used for?

Serdolect is used for treating schizophrenia. As Serdolect can affect your heart, your doctor will only prescribe Serdolect if you have not been able to continue taking another antipsychotic drug.

Ask your doctor if you have any questions about why you have been prescribed Serdolect.

2. BEFORE YOU TAKE SERDOLECT

Do not take Serdolect if:

- you are allergic (hypersensitive) to sertindole or any of the other ingredients of Serdolect (see section 6).
- you have a disturbed water or salt balance (too little potassium or magnesium in your blood), and your doctor is not treating you to correct this.
- you have a serious blood vessel disease or a serious heart disease such as heart failure, hypertrophy of the heart (thickening of the heart muscles), irregular heart-beats (arrhythmia), or an unusually slow heart rate (less than 50 beats per minute).
- your doctor has measured your heart beat with a heart trace (ECG) and has identified a prolongation of the QT-interval (a certain part of the ECG). Such a condition may be hereditary or may develop spontaneously.
- you have a severe liver disease.

- you take medicines that may prolong the QT-interval or may affect the amount of Serdolect in your blood. Examples of such medicines are:
 - medicines used for treating irregular heart beats (e.g. quinidine, amiodarone, sotalol, dofetilide).
 - antipsychotic drugs (e.g. thioridazine).
 - macrolide antibiotics (e.g. erythromycin, clarithromycin).
 - quinolone antibiotics (e.g. gatifloxacin, moxifloxacin).
 - antihistamine medicines used for treating hay fever or other allergies (e.g. terfenadine, astemizole).
 - azole antifungal medicines (e.g. ketoconazole, itraconazole).
 - medicines known as calcium channel blockers used for treating high blood pressure or chest pain (e.g. diltiazem, verapamil).
 - medicines such as lithium (used for treating manic-depression), cisapride (used for treating stomach problems), cimetidine (used for treating stomach ulcers), and indinavir (used for treating HIV).

Take special care with Serdolect:

- If you or someone else in your family has a history of blood clots, as medicines like Serdolect have been associated with formation of blood clots. If you have risk factors for stroke, such as high blood pressure, cardiovascular disorders or blood vessel problems in the brain.
- If you are above 65 years of age.
- If you have Parkinson's disease.
- If you have liver disease.

In elderly patients with dementia using antipsychotic medicine, there is an increased risk of stroke. Serdolect is not recommended for use in elderly patients with dementia.

Special care should also be taken to monitor physical health if you have diabetes. Your doctor will examine you, and let you know if Serdolect is right for you.

Before taking Serdolect, tell your doctor if:

- you have experienced fits (convulsions) either recently or in the past. In this case, a more cautious treatment with Serdolect will be necessary.

Physical health and Serdolect

Before and during your treatment with Serdolect, your doctor will conduct certain examinations in order to decide if it is safe for you. These examinations may include:

- a heart trace (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. The test will be repeated every 3 months and if your dose of Serdolect is increased or if the dose of other of your medicine is changed.
- a blood sample to check the amount of potassium and magnesium in your blood. If the amount of potassium or magnesium is too low, your doctor will need to treat this condition.
- a monitoring of your blood pressure.

What if I am taking other medicines?

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines can affect the amount of Serdolect in your blood. Therefore, when using Serdolect with the following medicines, particular care must be taken:

- dopamine agonists (used for treating Parkinson's disease) as their effect can be reduced by some antipsychotics.
- fluoxetine and paroxetine (used for treating depression) as they can cause the amount of Serdolect in your body to increase above normal levels. Your doctor may decide to decrease your dose of Serdolect.
- carbamazepine, phenytoin, and phenobarbitone (used for treating epilepsy) as well as rifampicin (an antibiotic most commonly used for treating tuberculosis, TB) as they can reduce the effect of Serdolect.

If your doctor changes the dose of any of your medicines, your doctor may also need to change the dose of Serdolect and do an ECG test.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The safety of Serdolect during pregnancy has not been established; therefore, Serdolect should not be used during pregnancy.

The following symptoms may occur in newborn babies of mothers that have used Serdolect in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

While you breast-feed, ask your doctor or pharmacist for advice before taking any medicine. Serindole is excreted in breast milk. If treatment with Serdolect is considered necessary, you should consider discontinuing breast-feeding.

Serindole can have side effects that may affect your sexual activity and fertility. These are not lasting effects. Please discuss any problems related to your sexual activity with your doctor.

Driving and using machines

Serdolect does not cause drowsiness. However, as with any new medicine, you should take care while driving or using machinery until you know how the medicine affects you.

Important information about some of the ingredients of Serdolect

This product contains lactose. If your doctor has told you that you have an intolerance to some sugars contact your doctor before taking Serdolect.

3. HOW TO TAKE SERDOLECT

Serdolect is taken once a day as a single daily dose. Serdolect can be taken with or without food, but if you take it with a meal this will help you remember to take it around the same time each day. Swallow the tablets with a drink of water.

Dosage

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

The usual starting dose is 4 mg a day. Every 4 to 5 days, the dose will be increased by 4 mg at a time until the maintenance dose has been reached.

The usual maintenance dose is 12 to 20 mg of Serdolect once a day. The dose prescribed by your doctor depends on your response to the medicine. Very rarely, your doctor may need to prescribe a maximum dose of 24 mg of Serdolect a day.

Elderly patients

Most likely, your doctor will increase the dose of your tablets over a longer period of time than normally recommended. Possibly, your doctor will also prescribe a lower maintenance dose than normally recommended.

Children and adolescents (under 18)

Serdolect is usually not given to children and adolescents.

Patients with special risks

If you have either mild or moderate liver problems, your doctor may want to monitor you more closely and will most likely increase your dose of Serdolect over a longer period of time than normally recommended. Possibly, your doctor will also prescribe a lower maintenance dose than normally recommended.

Serdolect can be given in usual doses to patients with kidney problems.

How long should I take Serdolect for?

Take the tablets for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Never change the dose of the medicine without talking to your doctor first.

If you take more Serdolect than I should

Symptoms of overdose may include:

- increased fatigue,
- slurred speech,
- increased pulse,
- lowering of the blood pressure.

If you think that you or anyone else may have taken too many Serdolect tablets, contact your doctor or your pharmacist immediately or go to the casualty department at your nearest hospital immediately. Do this even if there are no signs of discomfort or poisoning. Take the Serdolect container with you if you go to a doctor or hospital.

What if I forget to take Serdolect?

Do not take a double dose to make up for a forgotten dose. Contact your doctor if you forget to take your daily dose of Serdolect. Your doctor will make sure to restart your treatment the right way.

What if I don't want to take Serdolect anymore?

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

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

4. POSSIBLE SIDE EFFECTS

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

At the beginning of treatment with Serdolect, you may feel dizzy when you get out of bed or stand up. This feeling will most likely go away when you have taken Serdolect for a while. Your doctor will reduce the risk of your feeling dizzy by starting your tablets at a low dose and gradually increasing the dose over several weeks.

If the side effects are troublesome or last for more than a week or two, contact your doctor. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

If you experience any of the following symptoms, you should contact your doctor or go to the hospital straight away:

Uncommon (in less than 1 out of 100 patients):

- Very fast or uneven or forceful heartbeats, dizziness or fainting. You may also have shortness of breath or chest pain. These symptoms could indicate a life-threatening, irregular heartbeat
- Uncontrollable movements mainly of the mouth, tongue and limbs (this could indicate a condition known as tardive dyskinesia)

Rare (in less than 1 out of 1000 patients):

- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (these symptoms may indicate Neuroleptic Malignant Syndrome)

Unknown:

- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

In addition to above the following side effects have been reported:

Very common (in more than 1 out of 10 patients):

- rhinitis (nasal congestion)
- failure to ejaculate

Common (in less than 1 out of 10 patients):

- dizziness or sudden dizziness when standing up
- dry mouth
- weight gain
- shortness of breath
- swelling of hands or feet
- peculiar sensation in the skin like pins and needles
- decreased ejaculatory volume
- impotence

- changes in the electrical activity of your heart (called “QT prolongation”). QT prolongation can give rise to symptoms such as palpitation and fainting.
- red and white blood cells in the urine. This can be tested by your doctor, it is not visible to the naked eye.

Uncommon (in less than 1 out of 100):

- high blood sugar
- irregular heart beat known as Torsades de Pointes
- increased blood levels of a hormone called prolactin
- milky or clear discharge from breasts (galactorrhoea)

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Contact your doctor if you experience vomiting or diarrhoea, or if you take medicines known as diuretics (water tablets). They are usually used for treating high blood pressure or oedema (swellings when your body is keeping too much water). Your doctor may measure the amount of potassium in your blood.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE SERDOLECT

This medicinal product does not require any special temperature storage conditions.

Keep out of the reach and sight of children.

Do not use Serdolect after the expiry date, which is stated on the label or carton. The expiry date refers to the last day of the month.

Store in the original box or container in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 FURTHER INFORMATION

What Serdolect contains

The active substance is sertindole.

Each Serdolect film-coated tablet contains 4 mg, 12 mg, 16 mg or 20 mg sertindole.

The other ingredients are:

Tablet core: maize starch, lactose monohydrate, hypromellose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

Tablet coating: hypromellose, macrogol 400, titanium dioxide (white E171), and:

4 mg: iron oxide yellow (E172)
12 mg: iron oxide yellow (E172), iron oxide red (E172)
16 mg: iron oxide red (E172)
20 mg: iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172).

What Serdolect looks like and contents of the pack

Serdolect is presented as 4 mg, 12 mg, 16 mg and 20 mg film-coated tablets.

Description

4 mg tablets are oval, yellow, biconvex film-coated tablets marked with "S4" on one side
12 mg tablets are oval, beige, biconvex film-coated tablets marked with "S12" on one side
16 mg tablets are oval, rose, biconvex film-coated tablets marked with "S16" on one side
20 mg tablets are oval, pink, biconvex film-coated tablets marked with "S20" on one side.

Available pack sizes

4 mg 7, 10, 14, 20, 28, 30,50,98 or 100 tablets in blister pack.
 100 tablets in polypropylene container.
 100 tablets in polyethylene container.
12 mg: 7, 10, 14, 20, 28, 30, 50, 98 or 100 tablets in blister pack.
 100 tablets in polypropylene container.
 100 tablets in polyethylene container.
16 mg: 7, 10, 14, 20, 28, 30, 50, 98 or 100 tablets in blister pack.
 100 tablets in polypropylene container.
 100 tablets in polyethylene container.
20 mg: 7, 10, 14, 20, 28, 30, 50, 98 or 100 tablets in blister pack.
 100 tablets in polypropylene container.
 100 tablets in polyethylene container.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

H. Lundbeck A/S.
Ottiliavej 9,
DK-2500 Valby,
Denmark.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Representative office (Ireland)

Lundbeck (Ireland) Limited,
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland.

This medicinal product is authorised in the following member states of the EU/EEA under the following names:

| Name of the Member State | Name of the medicinal product |
|---------------------------------|--------------------------------------|
|---------------------------------|--------------------------------------|

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|-----------------|-----------|
| Austria | Serdolect |
| Belgium | Serdolect |
| Bulgaria | Serdolect |
| Czech Republic | Serdolect |
| Croatia | Serdolect |
| Denmark | Serdolect |
| Estonia | Serdolect |
| Finland | Serdolect |
| Germany | Serdolect |
| Greece | Serdolect |
| Hungary | Serdolect |
| Iceland | Serdolect |
| Ireland | Serdolect |
| Latvia | Serdolect |
| Luxembourg | Serdolect |
| The Netherlands | Serdolect |
| Norway | Serdolect |
| Poland | Serdolect |
| Romania | Serdolect |
| Slovakia | Serdolect |
| Spain | Serdolect |
| Sweden | Serdolect |
| United Kingdom | Serdolect |

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