

**PATIENT PACKAGE LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

This medicine is dispensed by a doctor's prescription only

**SERDOLECT**  
4mg Film-coated tablets  
Each tablet contains:  
Sertindole 4mg

**SERDOLECT**  
16mg Film-coated tablets  
Each tablet contains:  
Sertindole 16mg

Inactive ingredients: see section 6.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist. This medicine was prescribed for the treatment of your ailment. Do not pass it on to others. It can harm them even if it seems to you that their medical state is similar. The medicine is not usually intended for children and adolescents under the age of 18.

**1. WHAT IS THE MEDICINE INTENDED FOR?**

Serdolect is used for the treatment of schizophrenia in patients who are unable to take at least one other antipsychotic medicine.

**Therapeutic group:** Serdolect belongs to the antipsychotics group of medicines.

**2. BEFORE USING THE MEDICINE**

**Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients which the medicine contains (for the list of inactive ingredients, see section 6).
- you are pregnant (see "Pregnancy and breastfeeding" section).
- you have a disturbed salt and water balance (low blood potassium or magnesium level), which is not being treated by your doctor.
- you suffer from a severe disease of the blood vessels or from a severe heart disease, such as cardiac insufficiency, hypertrophy of the heart (thickening of the cardiac muscle), disturbed heart rate (arrhythmia) or an especially slow heart rate (less than 50 beats per minute).
- your doctor has checked your heart rate with an electrocardiogram (ECG) and has identified a prolongation of the QT-interval ( part of the ECG image). Such a condition may be hereditary or acquired.
- you suffer from a severe liver disease.
- you take a medicine that may prolong the QT-interval or may affect the Serdolect level in your blood (such as: quinidine, amiodarone, sotalol, dofetilide, thioridazine, erythromycin, clarithromycin, gatifloxacin, moxifloxacin, terfenadine, astemizole, ketoconazole, itraconazole, diltiazem, verapamil, lithium, cisapride, cimetidine, indinavir. See section "*Drug interactions*").

**Special warnings regarding use of the medicine**

-Before and during use of Serdolect, your doctor will conduct several examinations to ensure that Serdolect is safe for you to use. The examinations may include:

- ECG of the heart - electrocardiogram (ECG), in order to check that the QT-interval is not prolonged. This test will usually be repeated after 3 weeks of treatment with the medicine or when you reach a daily dosage of 16 mg of Serdolect and again after 3 months.

This test should be repeated every 3 months as well as in cases when the dosage of Serdolect was increased or in cases when the dosage of any other medicine you use is changed.

- a blood test to determine the level of potassium and magnesium. If the levels of potassium and magnesium are too low, the doctor will need to treat this condition.
- monitoring of blood pressure.

-At the beginning of treatment with Serdolect, you may feel dizzy when you get out of bed or stand up. This feeling usually passes sometime after starting Serdolect use. Your doctor will reduce the risk of feeling dizzy by starting at a low dosage and gradually increasing the dosage over several weeks.

-Studies show an increased risk of stroke in demented elderly patients who were treated with antipsychotics. Do not use Serdolect in demented elderly patients.

### **Before using Serdolect, tell the doctor if**

- you, or someone else in your family, suffer, or have suffered in the past, from formation of blood clots, as medicines of this type have been associated with formation of blood clots.
- you have diabetes (special care should be taken to monitor physical health if you have diabetes and using Serdolect).
- you suffer from Parkinson's disease.
- you have risk factors for a stroke (such as smoking, hypertension, cardiovascular disorders or blood vessel problems in the brain).
- you suffer from liver problem.
  - you suffer from epilepsy or experienced fits in the past: in this case a more cautious treatment with Serdolect will be necessary.
- you are over the age of 65.
- you are sensitive to any food or medicine.

### **Drug interactions**

**If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist.** It is especially important to inform the doctor or pharmacist if you are taking:

Do not use concomitantly with medicines that may prolong the QT-interval or affect Serdolect levels in your blood, such as (see also "Do not use the medicine if" section):

- medicines for the treatment of irregular heart rate (e.g. quinidine, amiodarone, sotalol, dofetilide).
- antipsychotics (e.g. thioridazine).
- macrolide antibiotics (e.g. erythromycin, clarithromycin).
- quinolone antibiotics (e.g. gatifloxacin, moxifloxacin).
- antihistamines used for treating hay fever or other allergies (e.g. terfenadine, astemizole).
- azol antifungal medicines (e.g. ketoconazole, itraconazole)

- medicines from the calcium channel blockers group for treatment of hypertension or chest pains (e.g. diltiazem, verapamil).
- lithium (for treatment of manic depression).
- cisapride (for treatment of stomach problems).
- cimetidine (for treatment of stomach ulcers).
- indinavir (for treatment of AIDS).

Additional medicines - consult the doctor or pharmacist if you are using or have recently used the following medicines:

- dopamine agonists (for treatment of Parkinson's disease).
- fluoxetine and paroxetine (for treatment of depression).
- carbamazepine, phenytoin, and phenobarbitone (for treatment of epilepsy).
- rifampicin (an antibiotic most commonly given for treatment of tuberculosis).
- diuretics (for treatment of hypertension).

If your doctor changed the dosage of any of your medicines, he may also have to change the dosage of Serdolect and do an ECG test.

### **Use of the medicine and food**

Serdolect can be taken with or without food.

### **Pregnancy breast-feeding and fertility**

If you are pregnant or breastfeeding, consult the doctor or pharmacist before taking any medicines.

Do not use Serdolect during pregnancy.

Consult the doctor if you are thinking of becoming pregnant during the treatment with Serdolect or if you discover that you are pregnant while under treatment.

The following signs may occur in newborn babies of mothers that have used Serdolect in the last trimester of pregnancy (the last 3 months of pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these signs, you may need to contact a doctor.

Sertindole (the active ingredient in Serdolect) is excreted into the breast milk. If you are taking Serdolect, you should consider discontinuing breastfeeding.

Sertindole 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 affect alertness. However, as with any new medicine, you should be cautious when driving a car or operating dangerous machinery until you know how the medicine affects you.

**Important information about some of the ingredients of the medicine**

The medicine contains lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking Serdolect. The lactose content in each tablet is detailed in section 6.

**3. HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the doctor's instructions.

You should check with the doctor or pharmacist if you are not sure.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is:

The recommended starting dosage is 4 mg per day.

Increase the dosage every 4-5 days by 4 mg until the maintenance dose is reached.

**Maintenance dose:**

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

**Do not exceed the recommended dose.**

**Elderly patients:**

It is most likely that your doctor will increase the dosage of your tablets over a longer period of time than normally recommended. Your doctor may even recommend a lower maintenance dose than normally recommended.

**Children and adolescents under the age of 18:**

**Serdolect is usually not given to children and adolescents.**

**Kidney problems:**

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

**Patients with special risks:**

If you suffer from either mild or moderate liver problems, your doctor will monitor you more closely and will most likely recommend increasing the dosage of the medicine over a longer period of time than normally recommended. In addition, your doctor will most likely recommend a lower maintenance dose than normally recommended.

**Directions for use:**

Take the medicine once a day as a single daily dose.

The medicine can be taken with or without food.

Do not chew! Swallow the tablets whole with a little water.

There is no information regarding the cutting or the crushing of the tablets.

**Duration of treatment:**

Complete the full course of the treatment recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor or pharmacist. Do not change the dosage of the medicine without consulting the doctor.

If you forgot to take Serdolect, do not take a double dose of Serdolect in place of the one you have forgotten. Refer to the doctor if you forgot to take the daily dose of Serdolect. The doctor will make sure that you resume taking the medicine in the most appropriate way.

**If you stop taking the medicine:**

Do not stop taking the medicine abruptly and without consulting a doctor.

Your doctor will decide when and how your treatment should be terminated to prevent unpleasant effects that may occur if treatment is stopped abruptly.

**Tests and check-ups**

Before and during use of the medicine, the doctor will refer you for examinations (see “**Special warnings regarding use of the medicine**” section).

**If you mistakenly took a higher dosage**, you may experience tiredness, slurred speech, increased heart rate, lowered blood pressure.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer to the doctor or to a hospital emergency room immediately and bring the package of the medicine with you. Do so even if you do not feel symptoms of overdose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions on the use of the medicine, consult the doctor or pharmacist.

**4. SIDE EFFECTS**

As with all medicines, use of Serdolect may cause side effects in some users. Do not be alarmed when reading the list of side effects; you may not experience any of 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 last for more than a week or two, contact your doctor.

While using Serdolect, **refer to the doctor or go to the hospital immediately if:**

- high fever developed, faster breathing, sweating, unusual stiffness of the muscles, drowsiness or sleepiness. This may indicate a rare condition known as neuroleptic malignant syndrome. This is a rare side effect (appears in less than 1 out of 1000 patients).
- you are having unusual mouth, tongue or limbs movements. This can indicate a condition called tardive dyskinesia - an effect which is uncommon (frequency of less than 1:100 patients).
- you feel irregular heartbeats - very fast or uneven or forceful heartbeats, or if you fainted or if you are having dizziness an effect which occurs uncommonly (frequency of less than 1:100 patients). You may also have shortness of breath or chest pain. These symptoms could indicate a life-threatening irregular heartbeat.

- formation of blood clots in the veins, especially in the legs (manifested by swelling, pain and redness of the leg). The blood clot may travel to a blood vessel in the lungs and cause chest pain or difficulty breathing (frequency- unknown). Seek medical treatment immediately if you feel any of these symptoms.

**Additional side effects:**

These side effects usually pass within a short time after the adaptation period to the preparation.

If these effects get worse, are bothersome or persist for more than one or two weeks, refer to the doctor.

Take notice of the effects detailed above, for which you must refer to the doctor immediately if they occur.

**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.

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

Increase in blood sugar level, disturbed heart rate of the Torsades de pointes type, 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 diarrhea, or if you take medicines known as diuretics (they are usually used for treating high blood pressure or oedema ). Your doctor may measure the amount of potassium in your blood.

If any of the side effects gets worse, or if you suffer from any side effects not listed in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site ([www.health.gov.il](http://www.health.gov.il)), which leads to an online form for reporting side effects. Alternatively you can use following link:

<https://sideeffects.health.gov.il/>

**5. HOW SHOULD THE MEDICINE BE STORED?**

- Avoid poisoning! This medicine and all other medicines must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instructions from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

- Storage conditions: store at a temperature below 30°C. Store the medicine in its original package to protect it from light.
- Do not discard of medicines in the regular waste; consult the pharmacist regarding how to discard of the remaining medicine which you no longer need. In this way, you will protect the environment.

## 6. **ADDITIONAL INFORMATION**

- In addition to the active ingredient, the medicine also contains:

### **Tablet core:**

maize starch, lactose monohydrate, hydroxypropylcellulose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

### **Tablet coating:**

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

Serdolect 4 mg: iron oxide yellow (E172)

Serdolect 16 mg: iron oxide red (E172)

Each film-coated Serdolect 4 mg tablet contains 60.78 mg lactose monohydrate.

Each film-coated Serdolect 16 mg tablet contains 95.08 mg lactose monohydrate.

### What Serdolect looks like and contents of the pack:

Serdolect 4 mg: oval, yellow, biconvex tablet, marked with "S4" on one side.

Serdolect 16 mg: oval, rose, biconvex tablet, marked with "S16" on one side.

The tablets are presented in a blister package (10, 14, 16, 20, 28, 30, 50, 98, 100 tablets).

Not all pack sizes are marketed.

- **License holder:** Lundbeck Israel Ltd., 11 Galgaley Haplada, P.O.B. 13105, Herzliya 4672211

- **Manufacturer:** H.LUNDBECK A/S, OTTILIAVEJ 9 , DK-2500 VALBY, DENMARK

Registration number of the medicine in the National Drug Registry of the Ministry of Health :

Serdolect 4 mg: 137 34 31470

Serdolect 16 mg: 137 36 31472

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