



4 mg, 12 mg, 16 mg, 20 mg

Film-coated tablets

Sertindole

THIS IS A MEDICAMENT

Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Serdolect is and what it is used for
2. Before you take Serdolect
3. How to take Serdolect
4. Possible side effects
5. How to store Serdolect
6. Further information

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 medicines help to correct certain chemical imbalances in the brain, which cause the symptoms of your illness.

What is Serdolect used for

Serdolect is used for treating schizophrenia.

Your doctor, however, may prescribe Serdolect for another purpose. Ask your doctor if you have any questions about why Serdolect has been prescribed for you.

2. BEFORE YOU TAKE SERDOLECT

Do not take Serdolect

- if you are allergic (hypersensitive) to sertindole or any of the other ingredients of Serdolect.
- if 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.
- if you have a severe blood vessel disease or a severe heart disease such as cardiac insufficiency, hypertrophy of the heart (thickening of the cardiac muscles), irregular heart-beats (arrhythmia), or an unusually slow heart rate (less than 50 beats per minute).
- if your doctor has measured your heart beat with an electrocardiogram (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.
- if you have a severe liver disease.
- if 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).
 - azol antifungal medicines (e.g. ketoconazole, itraconazole).
 - medicines known as calcium channel blockers and 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

Before and during your treatment with Serdolect, your doctor will conduct certain examinations in order to decide if treatment with Serdolect is safe for you. The 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. The test will be repeated every 3 months and if your dose of Serdolect is increased or if the dose of other of your medicines 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.

While taking Serdolect, you should contact your doctor:

- if you develop a high fever, unusual stiffness of the muscles, and disorder of your consciousness, especially if this occurs with sweating and fast heart rate. This may indicate a rare condition known as neuroleptic malignant syndrome. If you experience such symptoms, please contact your doctor immediately. Your doctor will probably stop your treatment with Serdolect.
- if you develop unusual movements of the body, mouth or tongue. Contact your doctor immediately if such symptoms occur, as such symptoms could indicate a condition known as Tardive Dyskinesia. Your doctor may choose to reduce your dose or stop your treatment with Serdolect.
- if you have experienced fits (convulsions) either recently or in the past. In this case, a more cautious treatment with Serdolect will be necessary.
- 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.
- 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 (when your body is keeping too much water). Your doctor may measure the amount of potassium in your blood.

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 of dizziness by starting your tablets at a low dose and gradually increasing the dose over several weeks.

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, caution should be exercised (see "Do not take Serdolect" in section 2):

- 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.
- 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 also may need to change the dose of Serdolect and do an ECG test.

Taking Serdolect with food and drink

Serdolect can be taken with or without food.

Pregnancy and breast-feeding

If you are pregnant, ask your doctor or pharmacist for advice before taking any medicine. The safety of Serdolect during pregnancy has not been established. Therefore, Serdolect should not be used during pregnancy. Consult your doctor if you are thinking about becoming pregnant or if you become pregnant while taking Serdolect.

While you breast-feed, ask your doctor or pharmacist for advice before taking any medicine.

Sertindole is excreted in breast milk. If treatment with Serdolect is considered necessary, you should consider no longer breast-feeding.

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

If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE SERDOLECT

How much to take

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

Initial phase

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.

Maintenance

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.

Kidney problems

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

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.

How and when to take Serdolect

Serdolect is taken once a day as a single daily dose. Serdolect can be taken with or without food. Swallow the tablets with a drink of water.

Duration of treatment

Your doctor decides the duration of treatment. Continue to 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 you should

Symptoms of overdosage 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.

If you forget to take Serdolect

Do not take a double dose of Serdolect 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.

If you stop taking Serdolect

Your doctor will decide 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 experience side effects but the side effects will usually disappear when you have taken Serdolect for a while.

If the side effects are troublesome or last for more than a week or two, contact your doctor. In addition, make sure to contact your doctor if you experience any of the symptoms mentioned in the section "Precautions for use".

Side effects, which have occurred during treatment with Serdolect, are listed below:

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

- rhinitis (nasal congestion)

Common (in more than 1 out of 100 patients):

- dizziness or 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
- prolonged QT-interval (change in the ECG)
- more red and white blood cells in the urine.

Uncommon (in less than 1 out of 100 but more than 1 out of 1000 patients):

- high blood sugar
- fainting
- fits or convulsions
- unusual movements of the body or mouth and tongue (this could indicate a condition known as tardive dyskinesia)
- a special kind of irregular heart beat known as Torsades de pointes

Rare (less than 1 out of 1000 but more than 1 out of 10,000 patients):

- high fever, unusual stiffness of the muscles and disorder of your consciousness, sweating and fast heart rate (neuroleptic malignant syndrome – see Take special care with Serdolect)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SERDOLECT

Always keep medicines out of the reach and sight of children.

Do not store above 25°C.

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

Do not use Serdolect after the expiry date, which is stated on the label or carton. 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 contain 4 mg, 12 mg, 16 mg or 20 mg sertindole.

The other ingredients are 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).

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

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 of Serdolect tablets

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

Serdolect is available in the following pack sizes

- 4 mg 30 tablets in blister pack 100 tablets in polypropylene container.
- 12 mg: 28 tablets in blister pack 100 tablets in polypropylene container.
- 6 mg: 28 tablets in blister pack 100 tablets in polypropylene container.
- 20 mg: 28 tablets in blister pack 100 tablets in polypropylene container.

Not all tablet strengths and pack sizes may be marketed

Manufacturer

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