PACKAGE LEAFLET: Information for the patient

PROSERTRA

Film-coated tablets – 50 mg

(Sertraline hydrochloride)

Read 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 only. 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 worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

In this leaflet:

1. WHAT PROSERTRA IS AND WHAT IT IS USED FOR

Prosertra contains the active substance sertraline hydrochloride which belongs to a group of drugs called selective serotonin reuptake inhibitors (SSRIs). These drugs are used to treat depression and / or anxiety disorders.

Prosertra is used in the treatment of:

- depression and prevention of recurrence of depression (in adults);
- social anxiety disorders (in adults);
- post-traumatic stress disorders (in adults);
- panic disorders (in adults);

- obsessive-compulsive disorders (in adults, children and adolescents aged 6 -17 years old).

Depression is a clinical condition with symptoms like: feeling sick, unable to sleep properly or to enjoy life as it should be.

Obsessive-compulsive disorders and panic disorders are illnesses linked to anxiety with symptoms like: being constantly troubled by persistent ideas (obsessions) that make you carry out repetitive rituals (compulsions).

Post-traumatic stress is a condition that can occur after a very emotionally traumatic experience, and has some symptoms that are similar to depression and anxiety.

Social anxiety disorder (social phobia) is an illness linked to anxiety. It is characterised by feelings of intense anxiety or distress in social situations (for example: when talking to strangers, when speaking in front of groups of people, when eating or drinking in front of others or worrying that you might behave in an embarrassing manner).

Your doctor has decided that this medicine is suitable for treating your illness.

You should ask your doctor if you are not sure why you have been given Prosertra.

2. BEFORE YOU TAKE PROSERTRA

Do not take Prosertra:

- if you are hypersensitive (allergic) to sertraline hydrochloride or to any of the excipients of this drug;
- if you are taking or have taken before medicines called monoamine oxidase inhibitors (MAOIs such as selegiline, moclobemide) or similar drugs (linezolid); if you stop treatment with Prosertra, you must wait until at least 1 week before you start treatment with a MAOI; if you stop the treatment with MAOI, you must wait at least 2 weeks before you can start treatment with Prosertra;
- if you are taking another medicine called pimozide (an antipsychotic drug).

Take special care with Prosertra

Ask your doctor before you take Prosertra, if you suffer from or have suffered in the past from any of the following conditions:

- serotonin syndrome; in rare cases this syndrome may occur when you are taking certain medicines at the same time with Prosertra (for symptoms, see section 4. “Possible side

effects"); your doctor will have told you whether you have suffered from this in the past;

- low levels of sodium in the blood, because this can occur during treatment with Prosertra; you should also tell your doctor if you are concomitantly taking antihypertensives, because these drugs may alter the sodium level in the blood; elderly people should be very careful as they are more at risk of having low sodium level in the blood;
- liver disease; in this case your doctor may advice you to lower the dose of Prosertra;
- diabetes; your blood glucose levels may be altered during Prosertra administration and the dose of the drugs that you take for the treatment of diabetes should be adjusted;
- epilepsy or a history of seizures; if you have a fit (seizure), contact your doctor immediately;
- if you have suffered from manic - depressive disease such as bipolar disorders or schizophrenia; in these cases contact your doctor immediately;
- if you have or have previously had suicidal thoughts (see below "Thoughts of suicide and worsening of your depression or anxiety disorder");
- if you have suffered from bleeding disorders or have taken before drugs for blood thinning such as aspirin or warfarin, because the risk of bleeding may increase;
- if you are a child or adolescent under 18 years old; Prosertra should only be used to treat children and adolescents aged 6-17 years old, only with a strict medical recommendation in obsessive - compulsive disorders;
- if you are having electroconvulsive therapy (ECT);
- if you have eye problems, such as glaucoma (increased pressure in the eye);
- if you have been told that you have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval;
- if you have heart disease, low potassium or magnesium levels, family history of QT prolongation, low heart rate and concomitant use of medications which prolong QT interval.

Restlessness / Akathisia

The use of Prosertra has been linked to akathisia (a distressing restlessness and need to move, often being unable to sit or stand still). This is most likely to occur during the first weeks of treatment. Increasing the dose may be harmful to patients who develop such symptoms.

Withdrawal symptoms

Withdrawal symptoms when treatment is stopped are common, particularly if the treatment is stopped suddenly. The risk of withdrawal symptoms depends on the duration of treatment, dosage, and the rate at which the dose is reduced. Generally, such symptoms are mild to moderate. However, they can be serious in some patients. They normally occur within the first few days after treatment discontinuation. In general, such symptoms disappear on their own and are reduced within 2 weeks. In some patients they may last longer (2 - 3 months or more). When stopping treatment with Prosertra**,** it is recommended to reduce the dose gradually over a period of several weeks or months, depending on the patient's needs.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to exert their effect, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself;
- if you are a young adult; information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Sexual problems

Medicines like Prosertra (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Use in children and adolescents

Prosertra should not usually be used in children and adolescents less than 18 years old, except for patients with obsessive-compulsive disorder. Patients under 18 years old have an increased risk

of undesirable effects, such as: suicide attempt, suicidal thoughts and hostility (mainly aggressiveness, oppositional behaviour and anger) when they are treated with this class of medicines. Nevertheless, it is possible that the doctor decides to prescribe Prosertra to a patient under 18 years old if it is in the patient's interest. If your doctor has prescribed Prosertra and you are less than 18 years old and you want to discuss this, please contact him/her. If any of the symptoms listed above appears or worsens when a patient under 18 years old is taking Prosertra, you should inform your doctor. Also, the long - term safety of sertraline in regard to growth, maturation and cognitive and behavioural development in this age group, has not yet been demonstrated.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Some medicines can affect the way Prosertra works, or Prosertra itself can reduce the effectiveness of other medicines taken at the same time.

Taking Prosertra together with the following medicines may cause serious side effects:

- medicines called monoamine oxidase inhibitors (MAOIs), like moclobemide (to treat depression), selegiline (to treat Parkinson’s disease), the antibiotic linezolid and methylene blue (to treat high levels of methaemoglobin in the blood); do not use Prosertra together with MAOIs;
- medicines to treat mental disorders (pimozide); do not use Prosertra together with pimozide.

Talk to your doctor especially if you are taking any of these drugs:

- medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy, and obesity);
- herbal medicines containing St. John’s Wort *(Hypericum perforatum)*; the effects of St. John’s Wort may last for 1-2 weeks; talk to your doctor;
- products containing the aminoacid tryptophan;
- medicines against severe pain (e.g. tramadol);
- medicines used in anaesthesia or to treat chronic pain (e.g. fentanyl, mivacurium and

suxamethonium);

- medicines for the treatment of migraine (sumatriptan);
- blood thinning medicines (warfarin);
- medicines against pain or arthritis (such as non-steroidal anti - inflammatory drugs like ibuprofen, acetylsalicylic acid (aspirin));
- sedatives (diazepam);
- diuretics;
- medicines for the treatment of epilepsy (phenytoin, phenobarbital, carbamazepine);
- medicines for the treatment of diabetes (tolbutamide);
- medicines for the treatment of excessive stomach acid and ulcers (cimetidine, omeprazole, lansoprazole, pantoprazole, rabeprazole);
- medicines for the treatment of maniac conditions and depression (lithium);
- other medicines for the treatment of depression (amitriptyline, nortriptyline, nefazodone, fluoxetine, fluvoxamine);
- medicines for the treatment of schizophrenia and other mental disorders (perphenazine, levomepromazine and olanzapine);
- medicines used to treat high blood pressure, chest pain or regulate the rate and rhythm of the heart (such as verapamil, diltiazem, flecainide, propafenone);
- medicines used to treat bacterial infections (such as rifampicin, clarithromycin, telithromycin, erythromycin);
- medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole);
- medicines used to treat HIV/AIDS and hepatitis C (protease inhibitors such as ritonavir, telaprevir);
- medicines used to prevent nausea and vomiting after an operation or chemotherapy (aprepitant);
- medicines known to increase the risk of changes in the electrical activity of the heart (e.g. some antipsychotics and antibiotics).

Taking Prosertra with food and drinks

Prosertra film-coated tablets can be taken with or without food.

Prosertra administration is contraindicated with alcohol.

Prosertra plasma levels are increased by grapefruit juice.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice if you think you are pregnant or you want to become pregnant. The doctor will advise you if you should continue to take Prosertra or not during pregnancy and breast - feeding, because the use of Prosertra is not safe.

Prosertra will only be given to you when pregnant if your doctor considers that the benefit for you is greater than any possible risk to the developing baby. Make sure your doctor knows you are on Prosertra.

Children exposed to sertraline, especially in the last trimester of pregnancy, may develop persistent pulmonary hypertension of the newborn (PPHN), which causes accelerated respiration and the blue colour of the skin of the child. These symptoms generally begin during the first 24 hours after the baby is born. If the neonate develops these symptoms, inform the doctor immediately.

Your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth.

Symptoms include:

- trouble with breathing,
- a blueish skin or being too hot or cold,
- blue lips,
- vomiting or not feeding properly,
- being very tired, not able to sleep or crying a lot,
- stiff or floppy muscles,
- tremors, jitters or fits,
- increased reflex reactions,
- irritability,
- low blood sugar.

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor who will be able to advise you.

There is evidence that sertraline passes into human breast milk. Prosertra should only be used in women during breast-feeding, if your doctor considers that the benefit exceeds any possible risk to the baby.
Some medicines like sertraline may reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines
Psychotropic drugs such as Prosertra may influence your ability to drive or use machines. You should therefore not drive or operate machines, until you know how this drug affects you.

3. HOW TO TAKE PROSERTRA
Always take Prosertra exactly as your doctor has told you. You can check with your doctor or pharmacist if you are not sure. If you feel that the effects of Prosertra are too strong or too weak, talk to your doctor or pharmacist.

Adults
For the treatment of depression and obsessive - compulsive disorders
The usual effective dose is 50 mg daily. This dose may be increased with 50 mg every 7 days in a period of weeks. The maximal recommended dose is 200 mg daily.

For the treatment of post-traumatic stress disorder, disorders in the control of panic, social anxiety disorders
The dose with which should be started the treatment of these conditions is 25 mg daily, and it is increased to 50 mg daily after one week. The daily dose may be increased with also 50 mg, but over a period of weeks. The maximal recommended dose is 200 mg daily.

Children and adolescents
Prosertra may be used for the treatment of obsessive-compulsive disorders in children of age 6 - 17 years old.

For the treatment of obsessive - compulsive disorders

Children aged 6 - 12 years old: the recommended starting dose is 25 mg daily. After one week, your doctor may increase this dose to 50 mg daily. The maximal recommended dose is 200 mg daily.
Adolescents aged 13 - 17 years old: the recommended starting dose is 50 mg daily. The maximal recommended dose is 200 mg daily.

If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.

Take your medication once daily either in the morning or evening.
Your doctor will also decide the duration of treatment that depends on the nature of your disease and how well you are responding to the treatment. It may take several weeks before your symptoms begin to improve. Treatment of depression should usually continue for 6 months after improvement.

If you take more Prosertra than you should
If you take more Prosertra than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken. Always take the carton box with you, even if there are no tablets in it.
Symptoms of overdose may include: drowsiness, nausea and vomiting, rapid heart rate, tremor, agitation, dizziness and in rare cases unconsciousness.

If you forget to take Prosertra
If you forget a dose (or more doses), take the following dose when it is time to take it usually. Do not take a double dose (or higher) to make up for a forgotten dose(s).

If you stop taking Prosertra
Do not discontinue the use of this drug without consulting your doctor initially. If you want to stop taking this drug, initially you should gradually reduce its dose over several weeks. If you stop abruptly the administration of the drug, you may experience side effects such as: dizziness, numbness, sleep disturbances, agitation or anxiety, headaches, feeling sick, being sick and

shaking. If you experience any of these side effects, or any other side effect whilst stopping taking Prosertra, please talk to your doctor.
If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Prosertra film - coated tablets can also cause side effects, although not everybody manifests them. 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.
Nausea is the most common side effect. The side effects depend on the dose and are often transient with continued treatment.

Tell your doctor immediately if you experience any of the following symptoms:

- a severe skin rash that causes blistering (erythema multiforme), (this can affect the mouth and tongue); these may be the symptoms of a serious disease called Stevens - Johnson syndrome or toxic epidermal necrolysis; your doctor will stop your treatment in these cases;
- allergic reaction with symptoms such as: itchy skin rash, breathing problems, wheezing, swollen eyelids, face or lips;
- agitation, confusion, diarrhoea, high temperature and blood pressure, excessive sweating and rapid heartbeat; these are symptoms of serotonin syndrome;
- yellow skin and eyes which may mean liver damage;
- depressive symptoms like suicidal ideas;
- preoccupation, nervosism, seizure, a manic episode.

The following side effects are noticed in clinical trials in adults:

Very common side effects (may affect more than 1 in 10 patients)
Insomnia, dizziness, sleepiness, headache, diarrhoea, feeling sick, dry mouth, ejaculation failure, fatigue.

Common side effects (may affect up to 1 in 10 patients)
Chest cold, sore throat, runny nose, anorexia, increased appetite, depression, feeling strange,

nightmare, anxiety, agitation, nervousness, decreased sexual interest, teeth grinding, numbness and tingling, shaking, abnormal taste, lack of attention, visual disturbance, ringing in the ears, palpitations, hot flush, yawning, abdominal pain, vomiting, constipation, upset stomach, gas, rash, increased sweating, muscle pain, sexual dysfunction, erectile dysfunction, chest pain, malaise, fever, weakness, back pain, weight increased, muscular movement problems (such as moving a lot, tense muscles and difficulty walking), injury, joint pain, menstrual irregularities.

Uncommon side effects (may affect up to 1 in 100 patients)
Intestinal problems, ear infection, cancer, hallucinations, feeling too happy, lack of caring, thinking abnormal, convulsions, involuntary muscle contractions, abnormal coordination, amnesia, decreased feeling, speech disorder, dizziness while standing up, migraine, ear pain, fast heartbeat, high blood pressure, flushing, breathing difficulty, possible wheezing, shortness of breath, oesophageal problem, difficulty swallowing, haemorrhoids, increased saliva, tongue disorder, burping, eye swelling, purple spots on skin, hair loss, cold sweat, dry skin, hives, osteoarthritis, muscular weakness / twitching, nighttime urination, unable to urinate, increase in urination, increase in frequency of urination, problem urinating, urinary incontinence, vaginal haemorrhage, female sexual dysfunction, chills, thirst, weight decreased, tooth disorder, tongue problem, bleeding problems (such as nose bleed, stomach bleeding, or blood in urine), swelling in legs.
Cases of suicidal ideation and suicidal behaviours have been reported during sertraline therapy or early after treatment discontinuation (see section 2).

Rare side effects (may affect up to 1 in 1.000 patients)
Swollen glands, high cholesterol, low blood sugar, physical symptoms due to stress or emotions, drug dependence, psychotic disorder, aggression, paranoia, sleeping walk, premature ejaculation, coma, abnormal movements, difficulty moving, increased sensation, sensory disturbance, glaucoma, tear problem, spots in front of eyes, double vision, light hurts eye, blood in the eye, unequal sized pupils, vision abnormal, heart attack, slow heart beat, heart problem, fainting, poor circulation of arms and legs, closing up of throat, breathing fast / slow, hiccups, sore mouth, tongue ulceration, mouth ulceration, problems with liver function, skin problem with blisters, hair rash, hair texture abnormal, skin odour abnormal, bone disorder, decreased urination,

urinary hesitation, dry vaginal area, red painful penis and foreskin, genital discharge, prolonged erection, breast discharge, hernia, drug tolerance decreased, abnormal laboratory tests, semen abnormal, relaxation of blood vessels procedure, pancreatitis, decrease in white blood cells, decrease in clotting cells, low thyroid hormones, endocrine problem, serious liver function problems, yellow jaundice, problems with clotting, severe allergic reaction, skin oedema, skin reaction to sun, itching.

Not known side effects (frequency cannot be estimated from the available data)
Lockjaw, bedwetting, partial loss of vision, inflammation of the colon (causing diarrhoea).

Side effects in children and adolescents
In clinical trials with children and adolescents, the side effects were generally similar to adults (see above). The most common side effects in children and adolescents were headache, insomnia, diarrhoea and feeling sick.

If you notice any of these side effects, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE PROSERTRA

Keep out from the reach and sight of children!
Do not use it after the expiry date, which is stated on the package.
Do not store above 25 °C!

6. FURTHER INFORMATION

What Prosertra 50 mg film-coated tablets contain:
The **active substance** is sertraline hydrochloride.
Each film-coated tablet contains 56 mg sertraline hydrochloride (corresponding to 50 mg sertraline).
The excipients are:
tablet core: microcrystalline cellulose, sodium starch glycolate, calcium hydrogen phosphate dihydrate, hydroxypropyl cellulose, polysorbate, magnesium stearate

film-coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, yellow iron oxide, red iron oxide, black iron oxide.

Contents of the pack

Carton box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,
St. “Skënder Vila”,
Tirana, Albania.
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