

PATIENT INFORMATION LEAFLET

Escitalopram Tablets IP (5/10/15/20 mg)

SEROPRAM 5/10/15/20

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Seropram 5/10/15/20 is and what it is used for
2. What you need to know before you take Seropram 5/10/15/20
3. How to take Seropram 5/10/15/20
4. Possible side effects
5. How to store Seropram 5/10/15/20
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1. What Seropram 5/10/15/20 is and what it is used for

Seropram 5/10/15/20 contains an active substance escitalopram. It belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Escitalopram is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

2. What you need to know before you take Seropram 5/10/15/20

Do not take Seropram 5/10/15/20:

- if you are allergic to escitalopram.
- if you take other medicines that belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and inozolind (an antibiotic).
- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG: an examination to evaluate how the heart is functioning).
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm

Warnings and precautions

Talk to your doctor or pharmacist before taking Seropram 5/10/15/20. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Seropram 5/10/15/20 should be stopped if seizures occur for the first time or if there is an increase in the seizure frequency
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Seropram 5/10/15/20 may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- if you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises.
- if you are receiving electroconvulsive treatment.
- if you have coronary heart disease.
- if you suffer or have suffered from heart problems or have recently had a heart attack.
- if you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- if you suffer from angle-closure glaucoma or have a history of glaucoma.

Please note:

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor. Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder

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

Children and adolescents

Seropram 5/10/15/20 should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility when they take this class of medicines. Despite this, your doctor may prescribe Seropram 5/10/15/20 for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Seropram 5/10/15/20 for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Seropram 5/10/15/20.

Other medicines and Seropram 5/10/15/20

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

Tell your doctor if you are taking any of the following medicines:

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranlycypromine as active ingredients.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
- "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain).
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke).
- Warfarin, dipyrindamole, and phenprocoumon (medicines used to thin the blood, so called anticoagulants).
- Neuroleptics (medicines to treat schizophrenia, psychosis) due to a possible risk of a lowered threshold for seizures, and antidepressants.
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life threatening heart rhythm disorder.

Do not take Seropram 5/10/15/20 if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparflaxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain anti-stimulants (astemizole, mizolastine). If you have any further questions about this, you should speak to your doctor.

Seropram 5/10/15/20 with food, drink and alcohol

Seropram 5/10/15/20 can be taken with or without food. As with many medicines, combining Seropram 5/10/15/20 with alcohol is not advisable, although Seropram 5/10/15/20 is not expected to interact with alcohol.

Pregnancy and breast-feeding and fertility

Inform your doctor if you are pregnant or planning to become pregnant. Do not take Seropram 5/10/15/20 if you are pregnant or breastfeeding unless you and your doctor have discussed the risks and benefits involved.

If used during pregnancy, Seropram 5/10/15/20 should never be stopped abruptly.

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.

Driving and using machines

You are advised not to drive a car or operate machinery until you know how Seropram 5/10/15/20 affects you.

3. How to take Seropram 5/10/15/20

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

Depression

The normally recommended dose of Seropram 5/10/15/20 is one tablet once daily. The dose may be increased by your doctor to a maximum of 20 mg per day.

Panic disorder

The starting dose of Seropram 5/10/15/20 is one tablet once daily. The dose may be further increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder

The normally recommended dose of Seropram 5/10/15/20 is one tablet once daily. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

Generalised anxiety disorder

The normally recommended dose of Seropram 5/10/15/20 is one tablet once daily. The dose may be increased by your doctor to a maximum of 20 mg per day.

Obsessive-compulsive disorder

The recommended dose of Seropram 5/10/15/20 is one tablet once daily. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly patients (above 65 years of age)

The recommended starting dose of Seropram 5/10/15/20 is one tablet once daily. You can take Seropram 5/10/15/20 with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

Duration of treatment

It may take a couple of weeks before you start to feel better. Continue to take Seropram 5/10/15/20 even if it takes some time before you feel any improvement in your condition. Do not change the dose of your medicine without talking to your doctor first. Continue to take Seropram 5/10/15/20 for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you take more Seropram 5/10/15/20 than you should

If you take more than the prescribed dose of Seropram 5/10/15/20, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Seropram 5/10/15/20 pack with you when you go to the doctor or hospital.

If you forget to take Seropram 5/10/15/20

Do not take a double dose to make up for forgotten doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

If you stop taking Seropram 5/10/15/20

Do not stop taking Seropram 5/10/15/20 until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Seropram 5/10/15/20 is gradually reduced over a number of weeks.

When you stop taking Seropram 5/10/15/20, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Seropram 5/10/15/20 is stopped.

Discontinuation symptoms include: Feeling dizzy (unsteady or off balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disoriented, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

If you experience the following side effects you should contact your doctor or go to the hospital straight away:

- ❖ Difficulties urinating, seizures (fits), yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis, fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

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

Very common (affects more than 1 user in 10):

- ❖ Feeling sick (nausea), headache

Common (affects 1 to 10 users in 100):

- ❖ Blocked or runny nose (sinusitis), decreased or increased appetite, anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin, diarrhoea, constipation, vomiting, dry mouth, increased sweating, pain in muscle and joints (arthralgia and myalgia), sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm), fatigue, fever, increased weight.

Reporting of side effects

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 Seropram 5/10/15/20

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Seropram 5/10/15/20 contains

The active ingredient is Escitalopram.

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to

Escitalopram 5mg

Colours: Carmoisine Lake & Titanium Dioxide

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to

Escitalopram 10mg

Colours: Sunset Yellow Lake & Titanium Dioxide

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to Escitalopram 15mg

Colours: Iron Oxide Red & Titanium Dioxide

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to

Escitalopram 20mg

Colours: Brilliant Blue Lake & Titanium Dioxide

What Seropram 5/10/15/20 looks like and contents of the pack

Seropram 5 is pink coloured, round, biconvex, film coated tablet. It is available in a strip using printed polyaminated foil on one side and plain aluminium foil on the other side. The pack size is 10 x 10 tablets in a printed carton.

Seropram 10 is light orange coloured, round, biconvex, film coated tablet with 'Q' logo scored on one side. It is available in a strip using printed polyaminated foil on one side and plain aluminium foil on the other side. The pack size is 10 x 10 tablets in a printed carton.

Seropram 15 is light red coloured, round, biconvex, film coated tablet with breakline on one side. It is available in a strip using printed polyaminated foil on one side and plain aluminium foil on the other side. The pack size is 10 x 10 tablets in a printed carton.

Seropram 20 is blue coloured, round, biconvex, film coated tablet with deep breakline on one side. It is available in a strip using printed polyaminated foil on one side and plain aluminium foil on the other side. The pack size is 10 x 10 tablets in a printed carton.



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