

PATIENT INFORMATION LEAFLET

Escitalopram Oxalate and Clonazepam Tablets IP
(5 mg/ 0.25 mg), (10 mg/ 0.25 mg), (10 mg/ 0.5 mg) & (20 mg/ 0.5 mg)

SEROPRAM LS/ PLUS/ FORTE/ HP

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 LS/ PLUS/ FORTE/ HP is and what it is used for
2. What you need to know before you take SEROPRAM LS/ PLUS/ FORTE/ HP
3. How to take SEROPRAM LS/ PLUS/ FORTE/ HP
4. What are the possible side effects of SEROPRAM LS/ PLUS/ FORTE/ HP
5. How to store SEROPRAM LS/ PLUS/ FORTE/ HP
6. Contents of the pack and other information

1. What SEROPRAM LS/ PLUS/ FORTE/ HP is and what it is used for

- SEROPRAM LS/ PLUS/ FORTE/ HP contains two different active ingredients, Escitalopram Oxalate and Clonazepam, used in treatment of Major Depression Disorder (MDD) and mixed anxiety disorder. It is the combination medicine that calms the brain by decreasing the abnormal and excessive activity of the nerve cells. It also works by increasing the level of a chemical messenger in the brain which improves mood.
- ❖ Escitalopram 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.
 - ❖ Clonazepam, which belongs to a group of medicines called Antiepileptics drug, Benzodiazepines derivatives. It is used to treat epilepsy in infants, children and adults.

2. What you need to know before you take SEROPRAM LS/ PLUS/ FORTE/ HP

Do not take SEROPRAM LS/ PLUS/ FORTE/ HP

- ❖ If you are allergic to Escitalopram Oxalate or Clonazepam.
- ❖ If you take other medicines which belong to a group called MAO inhibitors, including Selegiline (used in the treatment of Parkinson's disease), Moclobemide (used in the treatment of depression) and Linezolid (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
- ❖ If you have breathing problems or lung disease.
- ❖ If you have severe liver problems.
- ❖ If you have a condition called 'sleep apnoea syndrome' (where your breathing stops when you are asleep).

If you are not sure if the above applies to you, talk to your doctor or pharmacist before taking SEROPRAM LS/ PLUS/ FORTE/ HP.

Warnings and precautions

Talk to your doctor or pharmacist before taking SEROPRAM LS/ PLUS/ FORTE/ HP.

- ❖ If you have epilepsy. Treatment with Escitalopram 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 Escitalopram 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 or if you are pregnant
- ❖ 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 have a condition called 'myasthenia gravis' (where your muscles become weak and get tired easily).
- ❖ If you have ever had depression.

- ❖ If you have ever tried to kill yourself.
- ❖ If you regularly drink alcohol or take recreational drugs or you have had problems with alcohol or drug use in the past.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take SEROPRAM LS/ PLUS/ FORTE/ HP.

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 in sitting or standing 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 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 work, 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.

Children and adolescents

SEROPRAM LS/ PLUS/ FORTE/ HP 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 (predominately aggression, oppositional behaviour and anger) when they take this class of medicines.

Other medicines and SEROPRAM LS/ PLUS/ FORTE/ HP

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines taken without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ❖ Other medicines to treat epilepsy, such as Carbamazepine, Lamotrigine, Hydantoin, Phenytoin, Phenytoin, Primidone or Sodium Valproate.
- ❖ Cimetidine (used to treat stomach problems and heartburn).
- ❖ Rifampicin (an antibiotic used to treat infections).
- ❖ Medicines used to make you sleep (hypnotics).
- ❖ Medicines that help with anxiety (tranquillisers).
- ❖ Pain killers (analgesics) and medicines to relax your muscles (muscle relaxants).
- ❖ "Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder."
- ❖ "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine 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). These increase the risk of side effects.
- ❖ Cimetidine and Omeprazole (used to treat stomach ulcers), Fluvoxamine (antidepressant) and Ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Escitalopram.
- ❖ St. John's Wort (Hypericum perforatum) - a herbal remedy used for depression.
- ❖ Acetylsalicylic acid (aspirin) and non-steroidal Anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anticoagulants). These may increase bleeding tendency.
- ❖ Warfarin, Dipyridamole, and Phenprocoumon (medicines used to thin the blood, so called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Escitalopram in order to verify that your dose of anticoagulant is still adequate.
- ❖ Mefloquin (used to treat Malaria), Bupropion (used to treat depression) and Tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- ❖ Flecainide, Propafenone, and Metoprolol (used in cardiovascular diseases) Clomipramine, and Nortriptyline (antidepressants) and Risperidone, Thioridazine, and Haloperidol (antipsychotics).

SEROPRAM LS/ PLUS/ FORTE/ HP with alcohol

Do not drink alcohol while you are taking SEROPRAM LS/ PLUS/ FORTE/ HP. Alcohol can increase the effects of clonazepam, possibly leading to severe sedation that could result in

coma or death.

Pregnancy and breast-feeding

You must not take SEROPRAM LS/ PLUS/ FORTE/ HP if you are pregnant, might become pregnant or are breast-feeding, unless your doctor tells you to. Clonazepam is known to have harmful effects on the unborn child.

Driving and using machines

You are advised not to drive a car or operate machinery until you know how SEROPRAM LS/ PLUS/ FORTE/ HP affects you. This is because it can slow down your reactions, particularly when you start taking it. If you are in any doubt about whether you can do a particular activity, talk to your doctor.

Dependence

When taking this medicine there is a risk of dependence which increases with the dose and duration of treatment and also in patients with a history of alcohol and/or drug abuse.

3. How to take SEROPRAM LS/ PLUS/ FORTE/ HP

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

How to take this medicine

- ❖ SEROPRAM LS/ PLUS/ FORTE/ HP is taken once daily with or without food for the specified indication in adults.
- ❖ The recommended dose of Escitalopram is 10 mg/day in the initial stage of treatment. The dose should not be increased considering the presence of clonazepam.
- ❖ Initial dose of Clonazepam is 0.5 mg/day in the initial stages of treatment. Dosage of Clonazepam should not exceed 1 mg/day.
- ❖ Swallow SEROPRAM LS/ PLUS/ FORTE/ HP tablets whole with a glass of water. Do not chew, cut, or crush the tablets.

If you take more SEROPRAM LS/ PLUS/ FORTE/ HP than you should

If you take more SEROPRAM LS/ PLUS/ FORTE/ HP tablets than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. If you take too many tablets, you may feel drowsy, sleepy, and light-headed, have a lack of co-ordination or be less responsive than normal.

If you forget to take SEROPRAM LS/ PLUS/ FORTE/ HP

- ❖ If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule.
- ❖ Do not take a double dose of SEROPRAM LS/ PLUS/ FORTE/ HP to make up for a forgotten dose. Never take two doses at the same time.

If you stop taking SEROPRAM LS/ PLUS/ FORTE/ HP

Do not stop taking SEROPRAM LS/ PLUS/ FORTE/ HP until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of the tablets is gradually reduced over a number of weeks.

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 disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

4. What are the possible side effects of SEROPRAM LS/ PLUS/ FORTE/ HP

Like all prescription medicines, SEROPRAM LS/ PLUS/ FORTE/ HP may cause side effects.

Very common (may affect more than 1 in 10 people):

- ❖ Feeling sick (nausea),
- ❖ Headache

Common (may affect up to 1 in 10 people):

- ❖ Blocked or runny nose (sinusitis)
- ❖ Decreased or increased appetite
- ❖ Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, pricking 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)

Uncommon (may affect up to 1 in 100 people):

- ❖ Nettle rash (urticaria), rash, itching (pruritis)
- ❖ Grinding one's teeth, agitation, nervousness, panic attack, confusion state
- ❖ Disturbed sleep, taste disturbance, fainting (syncope)
- ❖ Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- ❖ Loss of hair, vaginal bleeding, Decreased weight
- ❖ Fast heart beat, Swelling of the arms or legs, Nosebleeds

Rare (may affect up to 1 in 1000 people):

- ❖ Aggression, depersonalisation, hallucination, Slow heart beat
- 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 LS/ PLUS/ FORTE/ HP

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 blister and carton after EXP.

Store this medicine below 30 °C.

The expiry date refers to the last day of that month.

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

The active ingredients are Escitalopram Oxalate and Clonazepam.

SEROPRAM LS

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to Escitalopram 5 mg

Clonazepam IP 0.25 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

SEROPRAM PLUS

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to Escitalopram 10 mg

Clonazepam IP 0.25 mg

Colours: Tartrazine Lake & Titanium Dioxide

SEROPRAM FORTE

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to Escitalopram 10 mg

Clonazepam IP 0.5 mg

Colours: Iron Oxide Yellow, Iron Oxide Red & Titanium Dioxide

SEROPRAM HP

Each film coated tablet contains:

Escitalopram Oxalate IP equivalent to Escitalopram 20 mg

Clonazepam IP 0.5 mg

Colours: Tartrazine Lake & Titanium Dioxide

What SEROPRAM LS/ PLUS/ FORTE/ HP looks like and contents of the pack

SEROPRAM LS is Light Yellow coloured, round, biconvex, film coated tablet with breakline on one side packed in Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.

SEROPRAM PLUS is Yellow coloured, round, biconvex, film coated tablet with breakline on one side packed in Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton

SEROPRAM FORTE is Red coloured, round, biconvex, film coated tablet with breakline on one side packed in Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton

SEROPRAM HP is Yellow coloured, round, biconvex, film coated tablet with breakline on one side packed in Alu-Alu Blister. The pack size is 10 x 10 tablets in a printed paper carton.



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