

ESOPLEX®

Escitalopram

ACTION

Exoplex is an anti depressant that belongs to a group of medicines called Selective Serotonin Reuptake Inhibitors (SSRIs) that work by normalizing levels of Serotonin in the brain. Serotonin abnormal level is key factor in developing depression and related disorders.

INDICATIONS

Depression

Exoplex is indicated in the treatment of depression. Depression is a disease characterized by low mood, fatigue or loss of energy, feelings of worthlessness, markedly diminished interest or pleasure, sleep disturbances and sometimes recurrent suicidal ideation. Depressed patients may further suffer from symptoms of anxiety.

Panic Disorder

Exoplex is indicated in the treatment of panic disorder. Panic disorder is characterized by recurrent unexpected attacks of intense fear or discomfort when the patient face particular situation or due to fear of experiencing new attacks. Exoplex is effective in relieving these symptoms and makes you feel better. Ask your doctor if you have any questions about why Exoplex has been prescribed for you as your doctor may have prescribed it for another illness.

DOSAGE AND ADMINISTRATION

Depression:

A dose of 10 mg per day is recommended and may be increased to a maximum daily dose of 20 mg.

Panic disorder:

A dose of 5 mg per day should be taken for the first week followed by increasing the dose to 10-15 mg per day. The dose may be increased to a maximum of 20 mg per day.

Elderly:

A starting daily dose of 5 mg is recommended with maximum daily dose kept below 20 mg.

Special population:

The initial daily dose of 5 mg for two weeks is recommended for patients with liver disease. The dose may be increased to 10 mg daily by your doctor if needed.

Note:

- Exoplex should not be given to children or adolescents (<18 years).
- Daily doses of Exoplex more than 20 mg have not been investigated.
- If you miss to take your daily dose, take the next dose at the usual time. Do not double your dose.

Method and Duration of Administration

Exoplex should be taken as a single once daily dose. Exoplex can be taken with or without food.

Exoplex tablets should be swallowed whole with a little water. Do not chew them.

Take Exoplex as instructed by your doctor.

Like other medicines for the treatment of depression and panic disorder, it may take few weeks before you feel any improvement. Therefore you should continue to take Exoplex as instructed by your doctor.

At least 6 months of treatment is recommended after you feel well again.

Note: Abrupt cessation of this kind of medications may cause discontinuation symptoms such as dizziness, nausea and headache. When you have completed your course of treatment it is therefore advised that the dose of Exoplex is gradually reduced over a couple of weeks.

CONTRAINDICATIONS

Don't take escitalopram if you are allergic to escitalopram or any of the other ingredients mentioned at the end of this leaflet, consult your doctor if you think you might be.

It is contraindicated to take escitalopram at the same time with the medications known as nonselective monoamine oxidase inhibitors (MAOIs), such as phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine which are also used for the treatment of depression. If you have taken any of these medicines you will need to wait 14 days before you start taking escitalopram. After stopping escitalopram you must allow 7 days before taking any of these medicines.

WARNINGS AND PRECAUTIONS

If your treatment is changed from the so-called selective MAO-A inhibitor, moclobemide, (also used in the treatment of depression) to escitalopram it is recommended that one day should elapse after you have finished taking moclobemide before you start taking your escitalopram tablets. After stopping escitalopram it is recommended to allow 7 days before starting moclobemide.

Despite of the recommendation, your doctor may decide that you should receive moclobemide concomitantly with escitalopram. This combination may in extraordinary cases prove beneficial. In such case, your doctor will prescribe low doses of both medicines at the start of the treatment.

If you experience symptoms like high fever, abrupt contractions of muscles with tremors, agitation and confusion while taking both moclobemide and escitalopram; you must stop taking both medicines and see your doctor immediately.

Medical problems

Please tell your doctor if you have any medical problem. Especially if you have a severe liver disease or diabetes, adjustment of the dose of medications for these diseases or your dose of escitalopram may be warranted.

Epilepsy or a history of seizures or fits

Seizures are a potential risk with all antidepressant medications. If you experience seizures or an increased frequency of seizures while being treated with escitalopram, it is important to inform your doctor.

The risk is further increased if you also take other medicines where the leaflet contains a warning similar to this one.

Episodes of mania

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity. In such cases, it is important to contact your doctor.

Subcutaneous bleeding

There have been reports that medicines like escitalopram may cause an increased incidence of subcutaneous bleeding (shown as e.g. increased tendency to develop bruises). The risk is increased if you have tendencies to develop bleedings, and if you also take medicines known to affect the rate of clotting of the blood (like aspirin, non-steroidal anti-inflammatory drugs (medicines used for pain relief) some anti psychotics or tricyclic antidepressants). The risk is also increased if you take ticlopidine, dipyridamole (both medicines are used to reduce the risk of thrombosis) or oral anticoagulants.

Alcohol

Escitalopram has not been shown to increase the effects of alcohol. Nevertheless, it is recommended not to drink alcohol during treatment with escitalopram.

Pregnancy and breast-feeding

Are you pregnant, trying to become pregnant or breastfeeding? If so, discuss the risks and benefits with your doctor before you start taking escitalopram. Pregnant women should not usually take escitalopram nor should mothers breast-feed their babies while taking this medicine.

Effects on ability to drive and use machines

Escitalopram does not cause drowsiness; however, as with any new medicine you should take care while driving or using machinery until you know how it affects you.

Drug Interactions

Please tell your doctor if you are taking or have taken any other medicines (including those purchased without prescription) during the last 14 days.

Escitalopram and the following medicines should be combined with caution:

- Lithium (used in the treatment of manic-depressive disorder) and selegiline (used in the treatment of Parkinson's disease); if you get high fever and abrupt contractions of muscles, feel agitated and confused you must see your doctor immediately.
- Imipramine and desipramine (both used to treat depression) and metoprolol (a so-called beta-blocker used in various cardiovascular diseases) are eliminated from the body more slowly when administered together with escitalopram, leading to increased amounts of these drugs in your body. If you receive both escitalopram and any of these medicines you should consult your doctor.
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain) increase the risk of side effects; if you get any unusual symptoms when using such medications with escitalopram you should see your doctor.
- Cimetidine (used to treat stomach ulcers) may cause increased blood levels of escitalopram if used at high doses at or above 800 mg per day. Although side effects of escitalopram have not been recorded, your doctor may decide to reduce your dose.
- St John's wort (hypericum perforatum - a herbal remedy used against low spirits); the risk of side effects may increase if you take escitalopram concomitantly with herbal remedies containing St John's wort.
- Oral anti-coagulants (medicines like warfarin used to treat e.g. blood clots in the legs/ lungs); the efficacy of the oral anti-coagulant may be altered, and your doctor will probably check the coagulation time of your blood when starting and discontinuing escitalopram in order to verify that your dose of anti-coagulant is still adequate.

SIDE EFFECTS

Few people may experience some side effects which are generally mild and usually transient:

Nausea, sinusitis, decreased appetite, difficulties falling asleep, feeling sleepy, dizziness, yawning, diarrhea, constipation, increased sweating, sexual disturbances (delayed ejaculation), fatigue, fever.

In addition to uncommon side effects such as disturbed sleep and taste perversion. There are number of side effects that are known to occur rarely with drugs that work in a similar way to escitalopram. These are:

Dizziness when you stand up due to low blood pressure, decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused), blurring of vision, vomiting, dry mouth, abnormal liver function test (increased amounts of liver enzymes in the blood), pains in muscles and joints. High fever, agitation, confusion, trembling and abrupt contractions of muscles may be signs of a rare condition called serotonin syndrome. Seizures, tremors, movement disorders (involuntary movements of the muscles), hallucinations, mania, anxiety, depersonalization, panic attacks, nervousness, difficulties urinating, flow of milk in women that are not nursing, rash, increased tendency to develop bruises, itching and patches of circumscribed swellings.

Note: If the side effects are troublesome or last for more than a week or two, tell your doctor. If you notice any other side effects not mentioned in this leaflet please tell your doctor or pharmacist.

OVERDOSAGE

If you or anyone take too many Exoplex tablets, you should contact your doctor directly or go to the nearest hospital even if there are no signs of discomfort.

STORAGE

Store in a dry place below 30°C.

PRESENTATIONS

Tablets

ESOPLEX 5: Escitalopram 5 mg/tablet

ESOPLEX 10: Escitalopram 10 mg/tablet

ESOPLEX 20: Escitalopram 20 mg/tablet

Excipients: Talc, Colloidal Silicon Dioxide, Croscarmellose Sodium, Microcrystalline Cellulose, Magnesium Stearate, Opadry White (03B28796).

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children
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