

Zelax[®]

Escitalopram

Zelax film-coated tablets

Each Zelax tablet contains either 10 mg or 20 mg of the active substance escitalopram as the oxalate salt.

Mechanism of action:

Escitalopram is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to normalize the levels of serotonin in the brain. Disturbances in the serotonin system of the brain are key factors in the development of depression and related disorders.

Use:

Zelax is used for the treatment of depression, panic disorder and social anxiety disorder (also called social phobia).

Depression is characterized by low/depressed mood, lack of energy, feeling low, feelings of little or no worth, sleeping disorders, withdrawal and being unable to cope with daily tasks. Depression may also be accompanied by suicidal thoughts. Depressed patients may further suffer from symptoms of anxiety. Panic disorder is characterized by patients developing unexpected attacks of intense panic or anxiety when faced with particular situations or due to the fear of experiencing new attacks. Precisely what triggers the attacks varies from patient to patient. The attacks recur when the patient faces the same situation again. Social Anxiety Disorder, also known as Social Phobia, is associated with excessive fear of social situations. Patients tend to avoid social situations that could cause anxiety or distress to themselves.

Zelax will relieve these symptoms and make you feel better.

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

Contraindications:

- Hypersensitivity to escitalopram.
- Concomitant use or within two weeks of monoamine oxidase inhibitors (MAOIs).

If you have taken any of these medicines you will need to wait 14 days before you start taking your Zelax tablets. After stopping Zelax you must allow 7 days before taking any of these medicines.

Warnings and precautions:

- Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with MDD (Major Depressive Disorder) and other psychiatric disorders.
- Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need.
- Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
- Families and caregivers should be advised to closely observe the patient and to communicate with the prescriber.
- This drug is not approved for any pediatric indication(s).

If your treatment is changed from the so-called selective MAO-A inhibitor, moclobemide, (also used in the treatment of depression) to Zelax it is recommended that one day should elapse after you have finished taking moclobemide before you start taking your Zelax tablets. After stopping Zelax it is recommended to allow 7 days before starting moclobemide. Although not generally recommended, it may happen that your doctor decides that you should receive moclobemide concomitantly with Zelax. This combination may in extraordinary cases prove beneficial. There exists, however, a risk of adverse effects from this combination. Therefore your doctor will usually prescribe low doses of both medicines at the start of the treatment. If you are treated with both moclobemide and Zelax and experience symptoms like high fever and abrupt contractions of muscles with tremors,

feel agitated and confused you must stop taking both medicines and see your doctor immediately.

Precautions for use:

• Medical problems

Please tell your doctor if you have any medical problems. Especially if you have a severe liver disease or diabetes, adjustment of the dose of medication for these diseases or your dose of escitalopram may be warranted. Also let your doctor know if you have coronary heart disease.

• Epilepsy or a history of seizures or fits

Seizures are a potential risk with all antidepressant medication. 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 moods 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 a bleeding tendency, 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 antipsychotics or tricyclic anti-depressants). The risk is also increased if you take ticlopidine, dipyridamole (both medicines are used to reduce the risk of thrombosis) or oral anticoagulants.

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 a 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 usual symptoms when using this combination 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 of escitalopram.
- St John's Wort (Hypericum perforatum - a herbal remedy used to treat low moods); 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.

Alcohol interactions:

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:

Pregnancy risk factor C.

If you are pregnant, trying to become pregnant or breast-feeding, discuss the risks and benefits with your doctor before you start taking escitalopram.

Pregnant woman should not usually take escitalopram nor should mothers breast-feed their babies while taking this medicine.

Driving and using 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.

How to take Zelax:

It is important to take your tablets as instructed by your doctor.

Dosage:

Adults

Depression:

The usual dose is 10 mg per day. This may be increased by your doctor. The recommended maximum dose is 20 mg per day.

Panic disorder:

The starting dose is 5 mg per day for the first week before increasing the dose to 10 mg per day. The dose may be increased by your doctor to a maximum of 20 mg per day. Patients who are prone to panic attacks may actually experience a temporary period of heightened anxiety after starting treatment, which generally resolves during the first 1-2 weeks. Therefore, a low starting dose is recommended in panic disorder.

Social anxiety disorder / Social phobia:

The usual dose is 10 mg per day. Usually 2-4 weeks are necessary to obtain symptoms relief. Depending on how you feel after you have taken your medicine for a while, your doctor might adjust your dose to between 5 mg and 20 mg daily.

Elderly patients

The usual starting dose is 5 mg per day. It is recommended that the maximum dose is kept below 20 mg.

Patients with special risks

It is recommended that patients with liver disease receive an initial dose of 5 mg daily for the first two weeks. Your doctor may increase the dose to 10 mg daily.

Children and adolescents (<18 years)

Escitalopram should not be given to children or adolescents.

Further considerations

The safety of daily doses of escitalopram in excess of 20 mg has not yet been thoroughly investigated. Therefore, your doctor will only prescribe higher doses after careful consideration of the necessity.

(For 5 mg dose, Zelax 10 tablet can be split into two halves).

Administration:

Administer once daily (morning or evening), with or without food. Swallow the tablets with a drink of water. Do not chew them.

Duration of treatment:

As with other medicines for the treatment of depression, panic disorder and social phobia it may take a few weeks before you feel any improvement. Therefore you should continue to take Zelax even if it takes some time before you feel any improvement in your condition.

Never change the dose of the medicine without talking to your doctor first.

The duration of treatment may vary for each individual. You should continue to take the tablets for as long as your doctor recommends, even if you begin to feel better. The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return.

Therefore it is recommended that treatment is continued for at least 6 months after you feel well again.

Special information relating to your disease:

Occasionally, thoughts of suicide or self-harm may occur or may increase in the first few weeks of treatment for depression, until the antidepressant effect becomes apparent. Tell your doctor immediately if you have any distressing thoughts or experiences.

Overdosage:

If you think that you or anyone else may have taken too many Zelax tablets contact your doctor or nearest hospital immediately. Do this even if there are no signs of discomfort. Take the Zelax box/container with you if you go to a doctor or hospital.

Missing dose:

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose.

Drug discontinuation:

Stopping this kind of medication quickly 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 Zelax is gradually reduced over a couple of weeks.

Possible side-effects:

Some people may experience unwanted effects (side-effects) whilst taking escitalopram.

The side-effects are generally mild and usually disappear after few days treatment. Please be aware that several of the effects may also be symptoms of your illness and therefore disappear when you start to get better.

If the side-effects are troublesome or last for more than a week or two, tell your doctor.

Side-effects seen in clinical trials include:

Very common (more than 1 out of 10)

Nausea

Common (less than 1 out of 10 but more than 1 out of 100):

Sinusitis (blocked or running nose), Decreased appetite, Difficulties falling asleep, Feeling sleepy, Dizziness, Yawning, Diarrhea, Constipation, Increased sweating, Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm), Fatigue, Fever.

Uncommon: (less than 1 out of 100)

Disturbed sleep, Altered taste.

If you notice any other side-effects not mentioned in this leaflet please tell your doctor or pharmacist.

In addition a number of side-effects are known to occur rarely with drugs that work in a similar way to escitalopram (the active ingredient of Zelax). 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, confusion, agitation, anxiety, loss of feeling of normality, panic attacks and nervousness
Difficulties urinating

Flow of milk in women that are not nursing

Rash, increased tendency to develop bruises, itchiness, small areas of swelling.

Storing conditions:

Store below 30 °C.

- A medicament is a product that 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 dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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