

LOXALATE

Escitalopram oxalate film coated tablets

5 mg, 10 mg, 20 mg



What is in this leaflet

This leaflet answers some common questions about LOXALATE.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LOXALATE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What LOXALATE is used for

LOXALATE is used to treat depression.

LOXALATE contains the active ingredient escitalopram oxalate. It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of

energy and feeling guilty over nothing.

LOXALATE corrects this chemical imbalance and may help relieve the symptoms of depression.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take LOXALATE

When you must not take it:

Do not take LOXALATE if you have an allergy to:

- any medicine containing escitalopram or citalopram
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOXALATE at the same time as the following other medicines:

- pimozide, a medicine used to treat mental disorders

- monoamine oxidase inhibitors (MAOIs), which are also used for the treatment of depression. Do not take LOXALATE when you are taking a MAOI or when you have been taking a MAOI within the last 14 days. Taking LOXALATE with MAOIs may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know when it is safe to start LOXALATE after the MAOI has been stopped.

Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

Herbal remedies containing St John's wort (*Hypericum perforatum*) should not be taken at the same time as this medicine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any medical conditions, especially the following:

- heart problems
- diabetes
- epilepsy
- liver problems
- kidney problems
- bipolar disorder (manic depression)
- bleeding disorders
- salt imbalances in the body
- restlessness

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you are receiving electroconvulsive therapy (ECT).

If you are pregnant or plan to become pregnant you need to discuss with your doctor the risks and benefits of taking LOXALATE during pregnancy. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like LOXALATE may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Tell your doctor if you are breastfeeding or wish to breastfeed. LOXALATE passes into breast milk. However, it is not known whether it may affect your baby. Your doctor will discuss the risks and benefits of taking LOXALATE when breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking LOXALATE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LOXALATE may interfere with each other. These include:

- bupropion, a medicine helping to treat nicotine dependence
- other antidepressants e.g. imipramine, desipramine, fluoxetine
- mefloquine, an anti-malaria medicine
- St John's Wort
- antipsychotics e.g. risperidone, thioridazine, haloperidol
- some heart medication e.g. metoprolol, flecainide, propafenone
- medicines used to treat reflux and ulcers e.g. omeprazole, lansoprazole, cimetidine
- aspirin and any non-steroidal anti-inflammatory agents (NSAIDs) e.g. ibuprofen
- ticlopidine and warfarin, medicines used to prevent blood clots
- tramadol, a medicine used to relieve pain
- sumatriptan, a medicine used to treat migraines
- lithium, a medicine used to treat mood swings and some types of depression
- tryptophan, an amino acid
- any other medicines that affect chemicals in the brain

These medicines may be affected by LOXALATE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines

to be careful with or avoid while taking this medicine.

How to take LOXALATE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

How much to take

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

The recommended maximum dose in elderly patients is 10 mg per day.

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.

How to take it

Swallow the tablets as a single daily dose with a glass of water. Do not chew the tablets.

LOXALATE 10 mg and 20 mg tablets can be divided in half if advised by your doctor or pharmacist.

Do not halve LOXALATE 5 mg tablets.

When to take it

Take LOXALATE as a single dose either in the morning or in the evening.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

LOXALATE can be taken with or without food.

How long to take it

Continue to take LOXALATE even if it takes some time before you feel any improvement in your condition.

Most medicines of this type take time to work so do not be discouraged if you do not feel better right away.

Individuals will vary greatly in their response to LOXALATE. Your doctor will check your progress at regular intervals.

The duration of treatment may vary for each individual, but is usually at least 6 months.

Continue taking your medicine for as long as your doctor tells you, 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.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much LOXALATE. Do this even if there are no signs of

discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea (feeling sick)
- vomiting
- dizziness
- agitation
- low blood pressure
- convulsions
- unconsciousness
- fast heart beats
- tremor

While you are using LOXALATE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LOXALATE.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Tell your doctor immediately if you have any suicidal thoughts or other mental or mood changes.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult, i.e. 18 to 24 years of

age, and you have not used antidepressant medicines before.

If you or someone you know demonstrates any of the following warning signs of suicide-related behaviour while taking LOXALATE, contact a health care provider immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation

Tell your doctor immediately if you experience symptoms such as restlessness or difficulty in sitting or standing still.

These symptoms can occur during the first weeks of treatment.

Contact your doctor as soon as possible if you suddenly experience an episode of mania. Some patients with bipolar disorder (manic depression) may enter into a manic phase.

This is characterised by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity.

Sometimes you may be unaware of the above-mentioned symptoms and therefore you may find it helpful to ask a friend or relative to help you to observe the possible signs of change in your behaviour.

Things you must not do

Do not take LOXALATE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor, even if you experience increased anxiety at the beginning of treatment.

At the beginning of treatment, some patients may experience increased

anxiety which will disappear during continued treatment.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as dizziness, nausea (feeling sick) and headache.

If possible, your doctor will gradually reduce the amount you take over several weeks or months before stopping the medicine completely.

Do not drink alcohol while you are taking this medicine.

Things to be careful of

Be careful driving or operating machinery until you know how LOXALATE affects you.

This medicine may cause dizziness, drowsiness and fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOXALATE.

This medicine helps most people with depression, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Side effects observed with LOXALATE are in general mild and disappear after a short period of time. They are most frequent during the first one or two weeks of treatment and usually decrease in intensity and frequency with continued treatment.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth
- decreased or loss of appetite
- difficulties sleeping
- fatigue, sleepiness or drowsiness, yawning
- nausea (feeling sick)
- diarrhoea
- constipation
- increased sweating
- sexual disturbances (problems with erection or ejaculation, decreased sexual drive and women may experience difficulties achieving orgasm)

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- agitation, confusion, panic attacks*, anxiety, restlessness*
- dizziness
- 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 feeling confused)*
- abnormal liver function tests (increased amounts of liver enzymes in the blood)*
- difficulty urinating*
- unusual secretion of breast milk*
- increased tendency to develop bruises*
- rash, itching, patches of circumscribed swellings
- fast or irregular heartbeats
- vision disturbances, eye pain or unusually dilated pupils

The above list includes uncommon but serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives)
- high fever, agitation, confusion, trembling and abrupt contractions of muscles (these symptoms may be signs of a rare condition called serotonin syndrome)*
- mania*, hallucinations
- seizures, tremors, movement disorders (involuntary movements of the muscles)*

The above list includes uncommon but very serious side effects. You may need urgent medical attention or hospitalisation.

The side effects marked with an asterisk () are a number of side effects that are known to occur with medicines that work in a similar way to LOXALATE.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

There is no evidence that LOXALATE is addictive, however, you may get side effects if you suddenly stop taking it. Tell your doctor if you get any side effects after stopping LOXALATE.

After using LOXALATE

Storage

Keep your tablets in the original container until it is time to take them.

If you take the tablets out of the container they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store LOXALATE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Loxalate 5 mg Tablets are normal convex white film coated tablets debossed "EC" over "5" on one side and "G" on the other.

Loxalate 10 mg Tablets are oblong normal convex white film coated tablets debossed "EC/10" on one side and "G" on the other.

Loxalate 20 mg Tablets are oblong normal convex white film coated tablets debossed "EC/20" on one side and "G" on the other.

Each blister pack contains 28 film coated tablets.

Ingredients

LOXALATE contains 5 mg, 10 mg and 20 mg of escitalopram as the active ingredient.

All tablets also contain:

- cellulose – microcrystalline
- silica – colloidal anhydrous
- talc – purified
- croscarmellose sodium
- magnesium stearate

The coating on each tablet, Opadry White, contains lactose.

Loxlate tablets are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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