

LOXALATE

Escitalopram oxalate film coated tablets

10 mg, 20 mg



What is in this leaflet

Please read this leaflet carefully before you start taking LOXALATE.

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 in adults.

LOXALATE tablets contain 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. This 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.

Your doctor may have prescribed LOXALATE for another reason.

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

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:

- pimozone, a medicine used to treat mental health disorders
- another anti-depressant medicine called a monoamine oxidase inhibitor (MAOI), or moclobemide (a reversible

MAOI). 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 a MAOI 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.

Ask your doctor or pharmacist if you are unsure as to whether or not you have been taking one of these medicines.

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 or have had any of the following medical conditions:

- heart problems
- kidney problems
- liver problems
- diabetes
- epilepsy or seizures
- bipolar disorder (manic depression)
- bleeding disorders

- salt imbalances in the body e.g. sodium, potassium or magnesium
- restlessness eye problems.

Escitalopram should be used with caution in patients at risk of irregular heart beat (e.g. QTc prolongation and Torsades de Pointes). Your doctor may wish to perform tests on the electrical activity of your heart prior to starting or during your treatment.

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).

Tell your doctor or if you are pregnant or plan to become pregnant. Your doctor can discuss with you the risks and benefits involved 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 your newborn baby has any of these symptoms, please contact your doctor immediately.

Tell your doctor if you are breastfeeding or wish to breastfeed. Like many other medicines, LOXALATE can pass into breast milk and 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 them before you start taking LOXALATE.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking LOXALATE.

Some medicines may interfere with LOXALATE. These include:

- Monoamine Oxidase Inhibitors (MAOIs) e.g. moclobemide, phenelzine, tranylcypromine
- pimozone
- bupropion, a medicine helping to treat nicotine dependence
- other antidepressants including tricyclic antidepressants and other SSRIs e.g. imipramine, desipramine, fluoxetine, nortriptyline, clomipramine, fluvoxamine
- mefloquine, an anti-malaria medicine
- St John's Wort (*hypericum perforatum*)
- antipsychotic medicines and medicines for mental health disorders e.g. risperidone, thioridazine, haloperidol, chlorpromazine, flupenthixol, zuclopenthixol and others
- some heart medication e.g. metoprolol, flecainide, propafenone
- medicines used to treat reflux and ulcers e.g. omeprazole, esomeprazole, lansoprazole, cimetidine
- aspirin and any non-steroidal anti-inflammatory agents (NSAIDs) e.g. ibuprofen

- ticlopidine and warfarin, and any other 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 LOXALATE works. You may need to take 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 for adults. 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.

Your doctor may tell you to take different doses to these. If so, follow their instructions.

How to take it

Swallow the tablets as a single daily dose with a full glass of water.

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

When to take it

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.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you to, even if it takes some time before you feel any improvement in your condition.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take LOXALATE for several months or even longer to make sure the benefits will last.

Continue taking your medicine until your doctor tells you to stop, 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.

While you are taking LOXALATE

Things you must do

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

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems

you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

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, between 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 or development of aggressive behaviour, irritability or agitation.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or new symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity or worsening of depression.

Contact your doctor as soon as possible if you suddenly experience an episode of mania. Some patients may have bipolar disorder (manic depression) and may enter into a manic phase. Mania may be characterised by a mood of overexcitement, over-activity and uninhibited behaviour,

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 change the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as dizziness, nausea (feeling sick), vomiting, headache, irritability, anxiety, agitation, emotional instability, fast or irregular heartbeat, difficulty sleeping, tingling, numbness or pins and needles in your hands and feet, tremor, confusion, diarrhoea, sweating and problems with your vision.

Your doctor may want you to gradually reduce the amount of LOXALATE you take over several weeks or months before stopping the medicine completely.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

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 and may affect alertness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

After you have stopped taking LOXALATE, you should still be careful for 1 or 2 weeks because

some of the medicine may still be in your blood stream.

It is not advisable to drink alcohol while you are taking LOXALATE.

Older people may become confused when taking LOXALATE. Families and carers should be aware of this. Special care may be needed.

In case of overdose

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. Take the pack of LOXALATE with you if you can.

Symptoms of an overdose may include:

- nausea (feeling sick)
- vomiting
- dizziness
- agitation
- low blood pressure
- convulsions
- unconsciousness
- fast or irregular heart beat
- tremor.

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 some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment 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.

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

- dry mouth
- decreased appetite or loss of appetite
- weight gain
- headache or migraine
- difficulties sleeping or abnormal dreaming
- fatigue, sleepiness or drowsiness, yawning
- stomach or bowel problems (e.g. nausea (feeling sick), vomiting, heartburn, indigestion, diarrhoea, constipation, flatulence, or abdominal or stomach pain)
- increased sweating
- tingling or numbness in hands and feet
- sexual disturbances (problems with erection or ejaculation, decreased sexual drive and women may experience difficulties achieving orgasm). In some cases these symptoms have continued after stopping treatment.
- chest infection, coughing, sore throat or difficulty swallowing
- runny or blocked nose, feeling of tension or fullness in the nose and cheekbones
- joint pain or swelling
- back pain
- flu like symptoms

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

- agitation, confusion, panic attacks*, anxiety, restlessness*, difficulty in sitting or standing still
- 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)*
- difficulty urinating*
- unusual secretion of breast milk*
- increased tendency to develop bruises*
- rash, itching, patches of circumscribed swellings
- fast or irregular heartbeats
- unusual vaginal bleeding
- vision disturbances, eye pain or unusually dilated pupils

The above list includes more 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* (refer to *While you are taking LOXALATE* section)
- hallucinations
- seizures, tremors, movement disorders (involuntary movements of the muscles)*
- vomiting blood or developing black or blood stained stools
- any attempts of self-harm (refer to *While you are taking LOXALATE* section)
- heart attack..

The above list includes 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.**

Tell your doctor if you get any side effects when stopping LOXALATE treatment.

There is no evidence that LOXALATE is addictive, however, you may get side effects if you suddenly stop taking it. An increased risk of bone fractures has been observed in patients over 50 years of age taking this type of medicine*.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

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

The lists of side effects mentioned above are not complete.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these side effects (for example, abnormal liver function or salt imbalances in the body) can only be found when your doctor does tests from time to time to check your progress

Do not be alarmed by this list of side effects. You may not experience any of them.

After using LOXALATE

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blisters 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 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.

Not all strengths may be marketed.

Ingredients

Active ingredient

LOXALATE contains 10 mg or 20 mg of escitalopram (as oxalate) as the active ingredient.

Inactive ingredients

All tablets also contain:

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

The tablet coating contains:

- lactose
- hypromellose
- titanium dioxide
- macrogol 4000

LOXALATE 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

LOXALATE is supplied in New Zealand by:

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

Telephone: (09) 579 2792

Date of Information

9 October 2019
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