

Loxalate

escitalopram oxalate

CONSUMER MEDICINE INFORMATION

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 benefits and risks. Your doctor has weighed the risks of you taking Loxalate against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Loxalate is used for

Loxalate is used to treat depression.

Loxalate belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). They are thought to work by their actions on brain chemicals called amines which are involved in controlling mood.

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 Loxalate has been prescribed for you.

Your doctor may have prescribed Loxalate for another reason.

Loxalate is available only with a doctor's prescription. Before you take Loxalate

When you must not take it

Do not take Loxalate if you are allergic to medicines containing escitalopram, citalopram or any of the ingredients listed at the end of this leaflet.

If you have an allergic reaction you may get:

- 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 if you are currently taking another medicine for depression known as a monoamine oxidase inhibitor (MAOI) or have taken one 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 convulsions (fits). Your doctor will

know when it is safe to start Loxalate after MAOI has been stopped.

MAOIs are medicines used to treat depression and Parkinson's disease. Some examples of MAOIs include moclobemide (e.g. Aurorix), phenelzine (Nardil), tranylcypromine (Parnate), selegiline (e.g. Eldepryl) and linezolid which is an antibiotic.

Do not take Loxalate if you are taking pimozone, a medicine used to treat mental disorders.

Do not take Loxalate 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.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Medicines like Loxalate have been shown to reduce the quality of sperm in animal studies, which theoretically could affect fertility. If you are intending to start a family, ask your doctor for advice.

Do not take LOXALATE if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

Make sure your doctor and/or midwife know you are on LOXALATE.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like LOXALATE may affect the general

condition of your newborn baby and 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 doctor and/or midwife immediately.

Your doctor will provide information to you regarding the use of Loxalate, during pregnancy. You should not stop taking your tablets until you have spoken to your doctor. Your doctor will discuss the possible risks and benefits of taking Loxalate during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Loxalate passes into breast milk. However, it is not known whether this may affect your baby. Your doctor will discuss the risks and benefits of taking Loxalate when breastfeeding.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- diabetes
- epilepsy
- liver problems
- kidney problems
- bipolar disorder (manic depression)
- bleeding or bruising disorders
- a history of seizures or fits
- restlessness and/or a need to move often
- raised intraocular pressure (fluid pressure in the eye), or if you are at risk of angle-closure glaucoma

you are receiving electroconvulsive therapy. 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 if you are taking any other medicines, including any that you buy without a prescription from a 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
- medicines used to treat reflux and ulcers, such as cimetidine, omeprazole, esomeprazole and lansoprazole
- medicines known to prolong bleeding, e.g. aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- ticlopidine and warfarin, medicines used to prevent blood clots
- fluconazole, an anti-fungal medicine
- mefloquine, an anti-malaria medicine
- sumatriptan, used to treat migraines
- tramadol, used to relieve pain
- medicines affecting the chemicals in the brain
- some heart medications, e.g. flecainide, propafenone, metoprolol
- tryptophan, an amino-acid
- lithium, used to treat mood swings and some types of depression
- medicines used to treat certain mental and emotional conditions, also called antipsychotics; e.g. risperidone, thioridazine and haloperidol
- medicines affecting nerves, also called neuroleptics e.g. prochlorperazine
- tricyclic antidepressants, e.g. imipramine, desipramine, clomipramine, nortriptyline
- St John's Wort (*Hypericum perforatum*), a herbal remedy

- other medicines for depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder.

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.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Use in children

Do not give Loxalate to children. Loxalate should not be given to children under 18 years of age as there is no specific information about such use. Always ask your doctor before giving medicines to children.

Use in elderly

Loxalate can be given to elderly patients with a reduced dose. The effects of Loxalate in elderly patients are similar to that in other patients.

How to take Loxalate

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack or bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Loxalate to take.

The usual dose is 10 mg per day. This may be increased by your doctor to 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. This dose may be increased to 10 mg daily.

Follow the instructions your doctor and pharmacist give you.

If you take the wrong dose, LOXALATE may not work as well and your condition may not improve.

How to take it

Swallow the tablets with a full 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.

When to take it

Take Loxalate 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 to remember when to take it.

Loxalate can be taken with or without food, either in the morning or evening.

How long to take it for

Continue taking your medicine for as long as your doctor tells you, even if you begin to feel better.

As with other medicines for the treatment of these conditions it may take a few weeks before you feel any improvement.

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

The length of treatment with Loxalate will depend on how quickly your symptoms improve.

Most medicines of this type take time to work, so do not be discouraged if you do not feel better right away. The treatment of depression may take at least six months.

Do not stop taking this medicine suddenly.

If LOXALATE is stopped suddenly you may experience mild, but usually temporary, symptoms such as dizziness, pins and needles, electric shock sensations, sleep disturbances (vivid dreams, inability to sleep), feeling anxious or agitated, headaches, feeling sick (nausea), vomiting, sweating, tremor (shaking), feeling confused, feeling emotional or irritable, diarrhoea, visual disturbances, or fast or irregular heartbeats.

When you have completed your course of treatment, the dose of LOXALATE is gradually reduced over a couple of weeks rather than stopped abruptly.

Your doctor will tell you how to reduce the dosage so that you do not get these unwanted effects.

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think 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 dizziness, low blood pressure, nausea (feeling sick), vomiting, agitation, tremor (shaking) and rarely convulsions and coma.

While you are taking Loxalate

Things you must do

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

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

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

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

A worsening of depressive symptoms including thoughts of suicide or self-harm may occur during initial treatment (generally the first one to two months) or when the doctor changes your dose. These symptoms should be controlled when the full effect of Loxalate takes place.

Children, adolescents or young adults under 25 years of age are more likely to experience these effects during the first few months of treatment.

Patients and caregivers should be alert and monitor for these effects.

If you or someone you know is showing any of the following warning signs of suicide while taking Loxalate, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- worsening of symptoms

- 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 any other unusual changes in behaviour or mood.

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

Keep all your doctor's appointments so that your progress can be checked.

Things you must not do

Do not stop taking Loxalate, or change the dose, without checking with your doctor. Do not let yourself run out of Loxalate over weekends or holidays.

If you stop Loxalate suddenly or reduce the dose too quickly, you may get unwanted side effects such as dizziness, sensory disturbances, sleep disturbances, agitation or anxiety tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, visual disturbances, nausea (feeling sick) and headache.

Your doctor will tell you how to gradually reduce the amount of Loxalate you are taking before stopping completely.

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

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

Things to be careful of

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

Loxalate may cause nausea, fatigue, dizziness, visual disturbances (such as blurred vision) or drowsiness in some people, especially early in the treatment. If you experience any of these, do not drive, operate

machinery or do anything else that could be dangerous.

Avoid alcohol while you are taking this medicine.

It is not advisable to drink alcohol while you are being treated with Loxalate.

Side effects

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

Loxalate helps most people with depression, but it may have unwanted side effects in a few people.

All medicines 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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- headache
- clogged or runny nose, sore throat
- flu-like symptoms
- decreased appetite
- dry mouth
- nausea (feeling sick), vomiting
- diarrhoea
- constipation
- abdominal pain, indigestion, flatulence
- back pain, joint pain
- difficulties falling asleep
- fatigue
- sleepiness or drowsiness, yawning
- increased sweating
- sexual disturbances (delayed ejaculation, problems with

erection, decreased sexual drive and women may experience difficulties getting orgasm)

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

- 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 confused)#
- abnormal liver function test (increased amounts of liver enzymes in the blood)#
- confusion, panic attacks#, anxiety, restlessness#, nervousness, agitation, abnormal dreams
- difficulties urinating#
- unusual secretion of breast milk#
- bleeding disorders including skin and mucous bleeding (e.g. bruising#) and a low level of blood platelets#
- increased tendency to develop bruises#
- rash, itching, patches of circumscribed swellings.
- dark stools with stomach pain
- changes in heart rate
- an increased risk of bone fractures has been observed in patients taking this type of medicine#

The above list includes 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.

- thoughts of harming yourself or thoughts of suicide#
- signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath

- high fever, agitation, confusion, trembling and abrupt contractions of muscles may be signs of a rare condition called serotonin syndrome#
- mania (elevated mood and associated symptoms)#
- hallucinations
- seizures, tremors, movement disorders (involuntary movements of the muscles)#
- fast, irregular heartbeat with feelings of dizziness or difficulty breathing

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

#The side effects marked with a hash (#) are rare side effects that are known to occur with medicines that work in a similar way to Loxalate.

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, if you suddenly stop taking Loxalate, you may get side effects. Tell your doctor if you get any side effects after stopping Loxalate.

After taking Loxalate

Storage

Keep Loxalate 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.

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

If you take the tablets out of the pack or bottle they may not keep well.

Keep your tablets protected from moisture in a cool dry place, where the temperature stays below 25 degrees C.

Do not store Loxalate or any other medicine in the bathroom or near a sink. Do not leave Loxalate in the car or on window sills.

Heat and dampness can destroy some 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 is available in 2 strengths:

Loxalate Tablets 10 mg:

9.5 mm x 5.5 mm oblong normal convex white film-coated tablet debossed "EC|10" on one side and "G" on the other, supplied in packs of 28 tablets.

Loxalate Tablets 20 mg:

12.5mm x 7 mm oblong normal convex white film-coated tablet debossed "EC|20" on one side and "G" on the other, supplied in packs of 28 tablets.

Ingredients

The active ingredient in Loxalate is escitalopram oxalate.

Loxalate tablets contain 10 mg or 20 mg of escitalopram (as escitalopram oxalate).

The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- colloidal anhydrous silica
- purified talc
- croscarmellose sodium
- magnesium stearate
- Opadry White OY-LS-28908 (ARTG No. 2596)

The coating on each tablet contains lactose monohydrate and contains traces of sulfites.

The tablets are gluten free. This medicine does not contain sucrose, tartrazine or any other azo dyes.

Manufacturer

Loxalate is made in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 – 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

- Loxalate 10 mg
AUST R 119964 (blister pack)
- Loxalate 20 mg
AUST R 119966 (blister pack)

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