LOXALATE®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking LOXALATE?

LOXALATE contains the active ingredient escitalopram. LOXALATE is used to treat depression.

For more information, see Section 1. Why am I taking LOXALATE? in the full CMI.

2. What should I know before I take LOXALATE?

Do not use if you have ever had an allergic reaction to escitalopram or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I take LOXALATE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LOXALATE and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take LOXALATE?

- Your doctor will decide what dose you will receive.
- The standard dose for this medicine is 10 mg per day. This may be increased by your doctor to 20 mg per day.

More instructions can be found in Section 4. How do I take LOXALATE? in the full CMI.

5. What should I know while taking LOXALATE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking LOXALATE. • If you become pregnant while taking LOXALATE, tell your doctor immediately. • Tell your doctor immediately if you have

	thoughts about killing yourself.
Things you should not do	• Do not stop taking this medicine suddenly or lower the dosage without telling your doctor. • Do not give the tablets to anyone else, even if they have the same condition as you. • Do not let yourself run out of medicine over the weekend or on holidays.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how LOXALATE affects you. • LOXALATE may cause visual disturbance (such as blurred vision), nausea, fatigue, and dizziness in some people, especially early in the treatment. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol	• Tell your doctor if you drink alcohol. • It is not advisable to drink alcohol while you are being treated for depression.
Looking after your medicine	• Store it in a cool dry place below 25°C, away from moisture. • Keep your tablets in the original packaging, in a safe place, away from children.

For more information, see Section 5. What should I know while taking LOXALATE? in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: decreased appetite or loss of appetite, dry mouth, diarrhoea, nausea, sleeplessness, fatigue, sleepiness or drowsiness, yawning, increased sweating, sexual disturbances.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following: thoughts of harming yourself or thoughts of suicide, serious allergic reaction, high fever, agitation, confusion, trembling and abrupt contractions of muscles, mania, hallucinations, seizures, tremors, movement disorders, fast, irregular heartbeat.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

LOXALATE®

Active ingredient: *escitalopram oxalate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LOXALATE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LOXALATE.**

Where to find information in this leaflet:

1. Why am I taking LOXALATE?
2. What should I know before I take LOXALATE?
3. What if I am taking other medicines?
4. How do I take LOXALATE?
5. What should I know while taking LOXALATE?
6. Are there any side effects?
7. Product details

1. Why am I taking LOXALATE?

LOXALATE contains the active ingredient escitalopram oxalate. 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.

LOXALATE is used to treat depression.

Depression is longer lasting 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.

LOXALATE may also be used to treat patients who may avoid and/or are fearful of social situations.

LOXALATE may also be used to treat patients who have excessive anxiety and worry.

LOXALATE may also be used to treat irrational fears or obsessional behaviour (obsessive-compulsive disorder). Obsessive-compulsive disorder involves having both obsessions and compulsions. Obsessions are unwanted thoughts that occur over and over again. Compulsions are the ongoing need to repeat certain actions as a result of these thoughts.

Your doctor, however, may prescribe it for another purpose.

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

2. What should I know before I take LOXALATE?

Warnings

Do not take LOXALATE if:

- you are allergic to escitalopram oxalate, citalopram, or any of the ingredients listed at the end of this leaflet.
- the packaging is torn or shows signs of tampering.

Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have allergies to any other substances such as foods, preservatives or dye.
  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.
- are pregnant or intend to become pregnant.
- have any other medical conditions.
- take any medicines for any other conditions.

If you have, or have had any of the following conditions, tell your doctor before starting LOXALATE:

- a tendency to bleed or bruise easily, or if you are pregnant (see 'Pregnancy and breastfeeding')
- diabetes
- heart disease
- kidney disease
- liver disease
- bipolar disorder (manic depression)
- 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.

Medicines like LOXALATE so called (SSRIs) may cause symptoms of sexual dysfunction (see Section 6. Are there any side effects?). In some cases, these symptoms have continued after stopping treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

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), such as phenelzine (Nardil), tranylcypromine (Parnate) and

moclobemide (e.g. Aurorix) which are also used for the treatment of depression.

- monoamine oxidase inhibitors such as linezolid which is an antibiotic and selegiline (e.g. Eldepryl) which is used in the treatment of Parkinson's Disease.

One day must elapse after you have finished taking moclobemide before you start taking LOXALATE. If you have taken any other MAOI you will need to wait 14 days. After stopping LOXALATE you must allow 14 days before taking any MAOI including moclobemide.

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.

Pregnancy and breastfeeding

Check with 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.

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.

If you take LOXALATE near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking LOXALATE so they can advise you.

If taken during pregnancy LOXALATE should never be stopped abruptly. You should not stop taking your tablets until you have spoken to your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not take LOXALATE if you are breastfeeding unless you and your doctor have discussed the risks and benefits. It passes into breast milk and therefore there is a possibility that your baby may be affected.

LOXALATE use in children and adolescents

Do not give LOXALATE to a child or adolescent

There is no experience with its use in children or adolescents under 18 years old.

LOXALATE use in the elderly

LOXALATE can be given to elderly patients over 65 years of age with a reduced dose.

The effects of LOXALATE in elderly patients are similar to those in other patients.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with LOXALATE and affect how it works. These include

- medicines used to treat nicotine dependence (e.g., bupropion)
- medicines used to treat reflux and ulcers such as, cimetidine, omeprazole, esomeprazole, and lansoprazole
- non-steroidal anti-inflammatory drugs (NSAIDs), known to prolong bleeding (e.g., aspirin and other NSAIDs)
- medicines used to prevent blood clots such as ticlopidine and warfarin
- anti-fungal medicines (e.g., fluconazole)
- anti-malaria medicines (e.g., mefloquine)
- medicines used to treat migraines (e.g., sumatriptan)
- medicines used to relieve pain (e.g., tramadol)
- medicines affecting chemicals in the brain

- some heart medicines such as flecainide, propafenone, metoprolol
- amino acids (e.g., tryptophan)
- medicines used to treat mood swings and some types of depression (e.g., lithium)
- antipsychotics, a class of medicines use to treat certain mental and emotional disorders such as risperidone, thioridazine, haloperidol
- tricyclic anti-depressants such as imipramine and desipramine
- St John's Wort (Hypericum perforatum), an herbal remedy
- any 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 to use different amounts of your medicines or take different medicines. Your doctor will advise you.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LOXALATE.

4. How do I take LOXALATE?

How much to take

- Your doctor will decide what dose you will receive.
- The standard dose for this medicine 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. Your doctor may increase the dose to 10 mg daily.
- Your doctor may have prescribed a different dose.
- Follow the instructions provided and use LOXALATE until your doctor tells you to stop.

When to take LOXALATE

- 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 should be taken as a single dose either in the morning or the evening.
- Take LOXALATE with or without food.

How to take LOXALATE

- Swallow the tablets whole with a full glass of water.
- Do not chew LOXALATE tablets.

How long to take LOXALATE

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

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

In some cases, the doctor may decide that longer treatment is necessary.

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.

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 LOXALATE

LOXALATE should be taken regularly at the same time each day. If you miss your dose at the usual time, and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally.

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

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 have taken too much LOXALATE

If you think that you have taken too much LOXALATE, 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.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26); New Zealand telephone 0800 POISON or 0800 764 766 for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking LOXALATE?

Things you should 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.

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

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

Persons taking LOXALATE may be more likely to think about killing themselves or actually trying to do so, especially when LOXALATE is first started (generally the first one to two months), or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone taking LOXALATE who talks about or shows signs of killing him or herself.

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.

Patients and care givers should pay attention for any of the following warning signs of suicide-related behaviour while taking LOXALATE. Tell your doctor immediately, or even 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 agitation, or any other unusual changes in behaviour or mood.

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.

Call your doctor straight away if you have:

- difficulties urinating
- seizures (fits)
- yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis
- become pregnant while taking LOXALATE

- have thoughts about killing yourself or if you are close to or care for someone taking LOXALATE who talks about or shows signs of killing him or herself
- experience symptoms such as restlessness or difficulty in sitting or standing still
- suddenly experience an episode of mania.

Remind any doctor, dentist or pharmacist you visit that you are taking LOXALATE.

Things you should not do

- Do not stop taking this medicine suddenly or lower the dosage without checking with your doctor.
- Do not give the tablets to anyone else, even if they have the same condition as you.
- Do not take LOXALATE to treat any other complaints, unless your doctor tells you to.
- Do not let yourself run out of medicine over the weekend or on holidays.

At the beginning of treatment, some patients may experience increased anxiety which will disappear during continued treatment.

Suddenly stopping LOXALATE may cause unwanted discontinuation symptoms such as dizziness, sensory disturbances, sleep disturbances, agitation or anxiety tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, visual disturbances, and nausea (feeling sick). Your doctor will tell you when and how LOXALATE should be discontinued. Your doctor will gradually reduce the

amount you are taking, usually over a period of one to two weeks, before stopping completely.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LOXALATE affects you.

LOXALATE may cause visual disturbance (such as blurred vision), nausea, fatigue, drowsiness and dizziness in some people, especially early in the treatment. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

It is not advisable to drink alcohol while you are being treated for depression.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Keep your tablets in the original pack until it is time to take them. If you take your tablets out of the pack, they may not keep well.

Store it in a cool dry place below 25°C away from moisture; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

It helps most people with depression, social anxiety disorder (social phobia), generalised anxiety disorder and obsessive-compulsive disorder, but it may have unwanted side effects in a few people.

The side effects of LOXALATE are, in general, mild and disappear after a short period of time.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• headache • clogged or runny nose, sore throat • flu-like symptoms • decreased appetite or loss of appetite • dry mouth • diarrhoea • nausea (feeling sick), vomiting • constipation • abdominal pain, indigestion, flatulence • back pain, joint pain • sleeplessness • fatigue, sleepiness or drowsiness, yawning • increased sweating • sexual disturbances (decreased sexual drive; problems with ejaculation or erection; women may experience difficulties achieving orgasm)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• agitation, confusion, panic attacks*, anxiety, restlessness*, abnormal dreams • dizziness • dizziness when you stand up due to low blood pressure* • fast heart rate or decrease in heart rate or irregular heartbeat • low sodium levels 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)* • dark stools with stomach pain • difficulties urinating* • unusual secretion of breast milk*	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• bleeding disorders including skin and mucous bleeding (e.g., bruising*) and a low level of blood platelets* • heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy and breastfeeding' in section 2 for more information • rash, itching, patches of circumscribed swellings • an increased risk of bone fractures has been observed in patients taking this type of medicine* • thoughts of harming yourself or thoughts of suicide* • serious allergic reaction (symptoms may include swelling of the face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, or hives)	

Serious side effects	What to do
• high fever, agitation, confusion, trembling and abrupt contractions of muscles (these symptoms may be signs of a rare condition called serotonin syndrome)* • mania (i.e.: 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 side effects marked with an asterisk (*) are a number of 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 else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems . By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What LOXALATE contains

Active ingredient **(main ingredient)**	**LOXALATE 5 mg:** • 5 mg escitalopram (as oxalate) per tablet **LOXALATE 10 mg:** • 10 mg escitalopram (as oxalate) per tablet **LOXALATE 20 mg:** • 20 mg escitalopram (as oxalate) per tablet

Other ingredients **(inactive ingredients)**	• colloidal anhydrous silica • croscarmellose sodium • magnesium stearate • microcrystalline cellulose • Opadry White OY-LS-28908 (ID: 2596) • purified talc
Potential allergens	Lactose and traces of sulfites.

Do not take this medicine if you are allergic to any of these ingredients.

What LOXALATE looks like

LOXALATE 5 mg is 5.5 mm normal convex white film coated tablet debossed "EC" over 5 on one side and "G" on the other (AUST R 119961).

LOXALATE 10 mg is 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 (AUST R 119964).

LOXALATE 20 mg is 12.5 mm x 7 mm oblong normal convex white film coated tablet debossed "EC|20" on one side and "G" on the other (AUST R 119966).

Who distributes LOXALATE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in November 2025.

LOXALATE® is a Viatris company trade mark

LOXALATE_cmi\Nov25/00