

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Esitalo.

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 this medicine 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 ESITALO IS USED FOR

Esitalo is used to treat depression.

It contains the active ingredient escitalopram oxalate.

It 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 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.

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

Esitalo may also be used to treat 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.

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

Esitalo is not addictive. However, if you suddenly stop taking it, you may get side effects.

Tell your doctor if you get any side effects after stopping Esitalo.

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

BEFORE YOU TAKE ESITALO

When you must not take it

Do not take this medicine if you have an allergy to:

- escitalopram, citalopram or to any of the other ingredients listed at the end of this leaflet under PRODUCT DESCRIPTION
- any other similar medicines (such as medicines of the same class, SSRIs).

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 Esitalo at the same time as the following other medicines:

- pimozide, a medicine used to treat mental disorders
- monoamine oxidase inhibitors (MAOIs), such as phenelzine, tranylcypromine and moclobemide which are also used for the treatment of depression
- medicines that are known to prolong the QT-interval.

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

Taking Esitalo 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 Esitalo after the MAOI has been stopped.

Do not take Esitalo if you have a known QT-interval prolongation or congenital long QT syndrome.

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 are pregnant or plan to become pregnant.

Do not take Esitalo if you are pregnant unless you and your doctor have discussed the risks and benefits involved. Make sure your doctor and/or midwife knows you are on Esitalo.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like Esitalo 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 used during pregnancy, Esitalo should never be stopped abruptly.

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Do not take Esitalo if you are breast-feeding unless you and your doctor have discussed the risks and benefits involved. It is not recommended that you breast-feed while taking Esitalo as it is excreted in breast milk.

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

- bleeding disorder: bleeding or bruising more easily than normal
- 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, difficulty sitting still.

Tell your doctor if you are receiving electroconvulsive therapy.

Do not give Esitalo to a child or adolescent.

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

Esitalo can be given to elderly patients over 65 years of age with a reduced dose. The effects of Esitalo in elderly patients are similar to that in other patients.

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

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 Esitalo 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)
- serious reactions, such as potentially life-threatening serotonin syndrome (characterised by neuromuscular excitation and altered mental status), have been reported when receiving escitalopram in combination with Monoamine Oxidase Inhibitors (MAOIs) or the reversible MAOI (moclobemide) and in patients who have recently discontinued escitalopram and have started MAOIs
- ticlopidine and warfarin, medicines used to prevent blood clots
- mefloquine, an antimalaria 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
- antipsychotics, a class of medicines used to treat certain mental and emotional conditions, e.g. risperidone, thioridazine and haloperidol
- tricyclic antidepressants, e.g. imipramine, desipramine
- St John's Wort (*Hypericum perforatum*), a herbal remedy
- any other medicines for depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder.

These medicines may be affected by Esitalo 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.

HOW TO TAKE ESITALO

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide what dose you will receive.

The standard dose for this medicine is 10mg per day. This may be increased by your doctor to 20mg per day.

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

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

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

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

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

When to take Esitalo

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

Taking it at about the same time each day will also help you remember when to take it.

Take Esitalo with or without food.

How long to take Esitalo

Continue to take Esitalo 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 Esitalo. 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.

Your doctor will tell you how to reduce the dosage so that you do not get unwanted effects. If Esitalo 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 heart beats.

When you have completed your course of treatment, the dose of Esitalo 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 you miss a dose and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally.

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

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

This may increase the chance of you getting an unwanted side effect.

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 or New Zealand 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 Esitalo. 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 ESITALO

Things you must do

Always follow your doctor's instructions carefully.

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

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

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

Tell your doctor immediately if you have thoughts about killing yourself or other mental or mood changes, or if you are close to or care for someone using Esitalo who talks about or shows signs of killing him or herself. Persons taking Esitalo may be more likely to think about killing themselves or actually trying to do so, especially when Esitalo is first started or the dose is changed or early after treatment discontinuation.

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 Esitalo, tell your doctor immediately, or go to the nearest hospital for treatment; patients and care givers should pay attention to these warning signs:

- 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 week 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 Esitalo to treat any other complaints unless your doctor tells you to.

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

Do not stop taking Esitalo, or lower the dosage, without checking with your doctor.

Do not change the dose 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.

Do not let yourself run out of medicine over the weekend or on holidays.

Suddenly stopping Esitalo may cause unwanted discontinuation symptoms such as dizziness, headache and nausea. Your doctor will tell you when and how Esitalo should be discontinued. Your doctor will gradually

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

Things to be careful of

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

It may cause 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.

Avoid alcohol while you are taking this medicine.

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

SIDE EFFECTS

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

It helps most people with depression and obsessive-compulsive disorder, 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.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

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

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

- decreased appetite or loss of appetite
- weight increase
- dry mouth
- diarrhoea, constipation
- nausea (feeling sick), vomiting
- tingling or numbness of the hands or feet
- sleeplessness
- fatigue, sleepiness or drowsiness, yawning
- abnormal dreams
- increased sweating
- nose bleeding
- sexual disturbances (decreased sexual drive; problems with ejaculation or erection; women may experience difficulties achieving orgasm).

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#
- a fast heart rate or decrease in heart rate or irregular heart beat
- 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)#
- difficulties urinating#
- unusual secretion of breast milk#
- bleeding disorders including skin and mucous bleeding (e.g. bruising#) and low level of blood platelets#

- rash, itching, patches of circumscribed swellings
- 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.

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, see also "Things you must do" section#
- 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 (i.e. elevated mood and associated symptoms)#
- hallucinations
- seizures, tremors, movement disorders (involuntary movements of the muscles)#
- fast, irregular heart beat with feelings of dizziness or difficulty breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

#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 Esitalo.

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.

AFTER TAKING ESITALO

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Esitalo 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.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Esitalo comes in two types of tablets:

- Esitalo 10mg film-coated tablets - oval, white, with breaking notch on one side.

- Esitalo 20mg film-coated tablets - round, white, with cross breaking notch on both sides.

Available in blister packs of 28 tablets.

Ingredients

Active ingredients:

- Esitalo 10mg tablets - 10mg escitalopram (as oxalate) per tablet
- Esitalo 20mg tablets - 20mg escitalopram (as oxalate) per tablet.

Inactive ingredients:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- magnesium stearate
- colloidal anhydrous silica
- titanium dioxide
- purified talc
- macrogol 6000.

This medicine does not contain gluten, sucrose, tartrazine or other azo dyes.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Tel: 1800 634 500

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PO Box 99102
Newmarket, Auckland 1149
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Australian Register Number(s)

Esitalo 10mg tablets: AUST R 146907 (blisters)

Esitalo 20mg tablets: AUST R 146908 (blisters).