

Esipram®

(ES-e-pram)

Escitalopram oxalate (ES-sigh-talo-pram OX-a-late)

Consumer Medicine Information

What is in this leaflet

This leaflet contains answers to some common questions about Esipram.

It does not contain all the information that is known about Esipram. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Esipram is used for

Esipram is used to treat depression.

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.

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

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

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

Esipram 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.

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

Esipram 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 Esipram.

Before you take it

When you must not take it

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

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, or rash, itching or hives on the skin.

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

- pimozone, 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.
- monoamine oxidase inhibitors such as linezolid which is an antibiotic and selegiline which is used in the treatment of Parkinson's Disease
One day must elapse after you have finished taking moclobemide before you start taking Esipram. If you have taken any other MAOI you will need to wait 14 days. After stopping Esipram you must allow 14 days before taking any MAOI including moclobemide. Taking Esipram 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 Esipram after the MAOI has been stopped.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

- 1. you have allergies to any other substances such as foods, preservatives or dyes.**
- 2. you are pregnant or intend to become pregnant.**

Medicines like Esipram 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 Esipram 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 Esipram.

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

3. you are breast-feeding or planning to breast-feed.

Do not take Esipram 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 Esipram as it is excreted in breast milk.

4. you have, or have had, the following medical conditions:

- a tendency to bleed or bruise easily
- 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.

5. you are receiving electroconvulsive therapy.

Do not give Esipram to a child or adolescent.

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

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

The effects of Esipram in elderly patients are similar to that in other patients.

If you have not told your doctor about any of the above, tell them before you use Esipram.

Taking other medicines

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

Some medicines and Esipram 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
- 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 Esipram, 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.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Esipram.

How to take it

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.

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, Esipram may not work as well and your condition may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

When to take it

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

Take Esipram with or without food.

How long to take it

Continue to take Esipram 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 Esipram. 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 Esipram 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 Esipram 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.

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 (Tel: 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Esipram.

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 it

Things you must do

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

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

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

Persons taking Esipram may be more likely to think about killing themselves or actually trying to

do so, especially when Esipram is first started 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 using Esipram 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 Esipram. Tell your doctor 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

Do not stop taking this medicine or change the dose without consulting 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.

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 give the tablets to anyone else, even if they have the same condition as you.

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

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

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

Suddenly stopping Esipram 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. Your doctor will tell you when and how Esipram 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 Esipram affects you.

It 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.

Avoid alcohol while you are taking this medicine.

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

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

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

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 Esipram are, in general, mild and disappear after a short period of time.

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

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

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 Esipram

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 a 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*

These may be serious side effects of Esipram. You may need urgent 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 section "Things you must do"
- 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.

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

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

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

You may not experience any of them.

After taking it

Storage

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

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

Keep Esipram tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp 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 Esipram, or the medicine has passed its expiry date, ask

your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Esipram comes in two types of tablets:

- Esipram 10 mg film-coated tablets - oval, white, scored and marked with "E" and "L" on each side of the score on one side of the tablet
- Esipram 20 mg film-coated tablets - oval, white, scored and marked with "E" and "N" on each side of the score on one side of the tablet

A box contains 28 tablets.

Ingredients

Active ingredient(s):

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

Inactive ingredients (tablets):

- microcrystalline cellulose
- croscarmellose sodium
- opadry OY-S28849 PI (4748) (contains: hypromellose, macrogol 400 and titanium dioxide)
- magnesium stearate
- colloidal anhydrous silica
- purified talc

Esipram does not contain lactose, gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Esipram is made by H. Lundbeck A/S, Denmark.

Esipram is supplied in Australia by:

CNS Pharma Pty Ltd
Level 5
Deutsche Bank Place
126 Phillip Street
Corner Hunter and Phillip Streets
Sydney NSW 2000
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Esipram tablets

10 mg - AUST R 128781

20 mg - AUST R 128783

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