

LEXAM

escitalopram oxalate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about LEXAM.

It does not contain all of 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 LEXAM against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine. You may need to read it again.

What LEXAM is used for

LEXAM is used to treat depression.

It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). These medicines work by their action 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 like 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.

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

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

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

LEXAM 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 may have prescribed this medicine for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

LEXAM is available only with a doctor's prescription.

There is no evidence that this medicine is addictive, however you may get side effects if you suddenly stop taking it.

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

Use in children and adolescents

LEXAM is not recommended for use in children and adolescents under 18 years of age, as the safety and efficacy of escitalopram in this age group has not been established.

Use in elderly

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

Before you take it

When you must not take it

Do not take LEXAM if you are allergic to medicines containing:

- escitalopram
- citalopram
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include 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.

Do not take LEXAM if you are taking other medications including:

- 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.

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

If you do take LEXAM while you are taking a MAOI, you may experience a serious reaction causing a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know when it is safe to start LEXAM after the MAOI has been stopped.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

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

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.

This medicine may affect the health of your newborn baby if you take it during pregnancy 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 LEXAM should never be stopped abruptly.

Medicines like Lexam 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 LEXAM if you are breastfeeding.

The medicine passes into breast milk and may affect your baby. Only take it if you have discussed the risks and benefits involved with your doctor.

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

- heart disease
- epilepsy or fits
- liver disease
- kidney disease
- diabetes
- manic depression (bipolar disorder)
- bleeding disorders.
- Restlessness and/or a need to move often
- You are receiving electroconvulsive therapy

Your doctor may want to take special care if you have any of these conditions.

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

Taking other medicines

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

Some medicines may be affected by LEXAM, or may affect how well it works. These include:

- bupropion, a medicine used to help stop smoking
- medicines used to treat reflux and ulcers, such as cimetidine, omeprazole, esomeprazole and lansoprazole
- medicines known to prolong bleeding, such as aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- ticlopidine and warfarin, medicines used to prevent blood clots
- sumatriptan, used to treat migraine
- tramadol, used to relieve pain
- tricyclic antidepressants, eg imipramine, desipramine
- mefloquine, an anti-malaria medicine
- medicines affecting the chemicals in the brain
- some heart medications, such as flecainide, propafenone, metoprolol
- antipsychotics, medicines to treat mental disorders, such as risperidone, thioridazine and haloperidol
- lithium, used to treat mood swings and some types of depression
- pain relievers, such as tramadol
- tryptophan, an amino acid
- St. John's Wort (*Hypericum perforatum*), an herbal remedy

- other medications for depression, anxiety, obsessive compulsive disorder or premenstrual dysphoric disorder.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take it

How much to take

Your doctor will tell you how much LEXAM to take.

The usual starting dose is 10 mg daily. Your doctor may increase the dose, depending on your response. The maximum recommended dose is 20 mg per day. In elderly patients, the maximum recommended dose is 10 mg per day.

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

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

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

How to take LEXAM

Swallow the tablets whole with a glass of water.

The tablets can be halved, but it is best not to crush or chew.

Take LEXAM as a single dose either in the morning or in the evening, with or without food.

How long to take it

Continue taking LEXAM 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 vary greatly in their response to LEXAM. Your doctor will check your progress at regular intervals.

The duration of treatment may vary, but is usually at least 6 months.

In some cases, the doctor may decide a longer treatment period.

Keep taking this medicine for as long as your doctor recommends, even if you begin to feel better.

The underlying illness may persist for a long time. If you stop your treatment too soon, your symptoms may return.

Do not stop taking it suddenly.

If Lexam 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 LEXAM 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 unwanted side 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 your tablets as you would normally the next day.

Otherwise, skip that day's dose but be sure to take the next day's dose when it is due. 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), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much LEXAM.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much LEXAM, you may have the following symptoms:

- nausea
- vomiting
- dizziness
- low blood pressure
- drowsiness
- agitation
- tremor
- convulsions or coma.

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking LEXAM.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking this medicine.

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

Persons taking LEXAM may be more likely to think about killing themselves or actually trying to do so, especially when LEXAM is first started or the dose is changed.

Tell your doctor immediately if you have any suicidal thoughts or other mental/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, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know is showing any of the following warning signs of suicide-related behaviour while taking LEXAM, it is important to contact a health care provider right away 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.

Tell your doctor immediately if you experience episodes of mania including a lot of rapidly changing thoughts or ideas, excessive physical activity, or exaggerated gaiety.

Some patients with manic-depressive illness may enter a manic phase and experience these symptoms. 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.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not stop taking LEXAM, or lower the dose, without checking with your doctor.

Stopping the medicine suddenly may cause withdrawal symptoms such as dizziness, headaches and

nausea. If your doctor decides to stop your treatment, he/she will usually recommend you to stop treatment by slowly reducing the dosage over a period of one to two weeks.

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

Do not use it to treat any other conditions unless your doctor tells you to.

Do not give your medicine 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 LEXAM 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 recommended that you 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 LEXAM.

This medicine helps most people with depression, social anxiety disorder and generalised anxiety disorder and obsessive-compulsive disorder, 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.

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:

- nausea
- difficulty in falling asleep
- feeling sleepy, drowsiness, fatigue, yawning
- diarrhoea
- dry mouth
- sexual disturbances (decreased sex drive, in men - delayed ejaculation or problems with erection; in women – difficulty in getting orgasm).
- decreased or loss of appetite
- increased sweating

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 LEXAM.

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*
- low 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) *
- difficulty urinating*
- unusual secretion of breast milk*
- bleeding disorders including skin mucous bleeding (e.g. bruising*) and low levels of blood platelets*
- rash, itching, hives, patches of circumscribed swelling.
- Fast heart rate or decrease in heart rate or irregular heart beat
- An increased risk of bone fractures has been observed in patients taking this type of medicine*

These are serious side effects and you may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- allergic reaction, the symptoms of which may include swelling of the face, lips, mouth or throat which can cause difficulty in swallowing or breathing
- high fever, agitation, confusion, trembling and abrupt contractions of muscles, symptoms of a rare condition called serotonin syndrome
- mania*, hallucinations
- seizures, tremors, movement disorders (involuntary movements of the muscles) *
- fast, irregular heart beat with feelings of dizziness or difficulty breathing.
- Thoughts of harming yourself or thoughts of suicide*, see also section "Things you must do"

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

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

Other side effects not listed above may also occur in some patients.

An increased risk of bone fractures has been observed in patients taking medicines like LEXAM.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After using it

Storage

Keep LEXAM 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 blister pack until it is time to take them.

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

Do not store LEXAM or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking it, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

LEXAM comes in two strengths of tablets:

- 10 mg tablet - white, oval convex shaped, coated tablet with 'E' bisect '1' on one side and plain on the other side
- 20 mg tablet - white, oval convex shaped, coated tablet with 'E' bisect '2' on one side and plain on the other side.

Each pack contains 28 tablets.

Ingredients

The active ingredient in LEXAM is escitalopram (as oxalate):

- each LEXAM 10 tablet contains 10 mg of escitalopram

- each LEXAM 20 tablet contains 20 mg of escitalopram.

The tablets also contain:

- microcrystalline cellulose
- colloidal anhydrous silica
- purified talc
- croscarmellose sodium
- magnesium stearate
- Opadry II complete film coating system 85F28751 WHITE (ARTG No 1027).

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Australian registration numbers:
LEXAM 10 - AUST R 211387
LEXAM 20 - AUST R 211388

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