

LEXAPRO FILM-COATED TABLETS

Escitalopram (as oxalate) (5, 10, 15, 20mg)

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What Lexapro is used for

Lexapro contains escitalopram and is used to treat:

- depression
- panic disorder with or without agoraphobia (fear of public or open spaces)
- social anxiety disorder/social phobia (fear or avoidance of social situations)
- generalised anxiety disorder (generally feeling very anxious or nervous, even when there is little or no reason to worry about them)
- obsessive-compulsive disorder (OCD) (persistent, obsessive thoughts that make you carry out repetitive behaviour)

How Lexapro works

Lexapro contains the active substance escitalopram. Lexapro belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Before you use Lexapro

- When you must not use it

Do not take:

- if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section **Product Description**).
- If you take other medicines which belong to a group called monoamine oxidase inhibitors (MAOIs) (see subsection Taking other medicines). Taking Lexapro with a MAOI may cause a serious, sometimes fatal, reaction with features resembling serotonin syndrome (see section **Side effects**).

- at the same time as taking pimozide (used in the treatment of mental disorders or nervous system disorders)

- Before you start to use it

Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Lexapro should be stopped if seizures (fits) occur for the first time, or if there is an increase in the seizure frequency (see also section **Side effects**).
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Lexapro may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- if you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises.
- if you are receiving electroconvulsive treatment (ECT) (usually used for severe depression).
- if you have coronary heart disease.

[see also subsection Things to be careful of].

- if you have a history of mania (uncontrollable excitement that causes unusual behaviour) or hypomania (a condition similar to mania but less severe)
- if you have a history of suicide-related events
- if you are currently pregnant, breast-feeding, or trying to get pregnant.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- Non-selective MAOIs, e.g. phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Lexapro. After stopping Lexapro you must allow 7 days before taking any of these medicines.
- Reversible, selective MAO-A inhibitors, e.g. moclobemide (used to treat depression).

- Irreversible MAO-B inhibitors, e.g. selegiline (used to treat Parkinson's disease).
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan (an amino acid).
- Desipramine (used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Lexapro.
- St John's Wort (*Hypericum perforatum* - a herbal remedy used for depression).
- Acetylsalicylic acid, non-steroidal anti-inflammatory drugs (NSAID), warfarin, dipyridamole, and phenprocoumon (medicines used for pain relief or to thin the blood). These may increase bleeding-tendency.
- Mefloquin (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat mental disorders) and anti-depressants due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants), and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Lexapro may need to be adjusted.

How to use Lexapro

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use

Adults

Depression

The normally recommended dose of Lexapro is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

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Panic disorder

The starting dose of Lexapro is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder

The normally recommended dose of Lexapro is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

Generalised anxiety disorder

The normally recommended dose of Lexapro is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Obsessive-compulsive disorder

The normally recommended dose of Lexapro is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly patients (above 65 years of age)

Initial treatment with half the usually recommended dose and a lower maximum dose are recommended.

Use in children and adolescents

Lexapro should not normally be given to children and adolescents (see subsection *Things to be careful of*).

If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.



- When to use it

You can take Lexapro with or without food. Swallow the tablet with some water.

As with many medicines, combining Lexapro with alcohol is not advisable, although Lexapro is not expected to interact with alcohol.

- How long to use it

It may take a couple of weeks before you start to feel better. Continue to take Lexapro even if it takes some time before you feel any improvement in your condition for as long as your doctor recommends.

If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

- If you forget to use it

Do not take a double dose to make up for forgotten doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

- If you use too much (overdose)

If you take more than the prescribed dose of Lexapro, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion (fits), coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Lexapro box/container with you when you go to the doctor or hospital.

While you are using it

- Things you must do

- Take Lexapro exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Lexapro.
- Tell your doctor immediately if you become pregnant while taking Lexapro.

- Things you must not do

Do not change the dose of your medicine without talking to your doctor first.

Do not stop taking Lexapro until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Lexapro is gradually reduced over a number of weeks. When you stop taking Lexapro, especially if it is abruptly, you may feel discontinuation symptoms. Most people find that the

symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Lexapro, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Pregnancy, breast-feeding and fertility

Do not take Lexapro if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved. Make sure your midwife and/or doctor know you are on Lexapro. If used during pregnancy Lexapro should never be stopped abruptly.

If you take Lexapro during your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. When taken during pregnancy, medicines like Lexapro 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

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begin during the first 24 hours after the baby is born.

If your newborn baby has any of these symptoms, please contact your midwife and/or doctor immediately. It is expected that Lexapro will be excreted into breast milk. Breastfeeding is not recommended during the treatment.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet. Ask your doctor or pharmacist for advice before taking any medicine.

Children and adolescents

Lexapro should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Lexapro for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Lexapro for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Lexapro. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Lexapro in this age group have not yet been demonstrated.

Driving and using machines

You are advised not to drive a car or operate machinery until you know how Lexapro affects you.

Please note:

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor. Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor

immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

If you experience the following side effects you should contact your doctor or go to the hospital straight away:

Uncommon (may affect up to 1 in 100 people):

- Unusual bleeds, including gastrointestinal bleeds

Rare (may affect up to 1 in 1,000 people):

- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic

reaction), contact your doctor or go to a hospital straight away.

- If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome. If you feel like this contact your doctor.

Not known (frequency cannot be estimated from the available data):

- Difficulties urinating
- Seizures (fits)
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis

In addition to above the following side effects have been reported:

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea)

Common (may affect up to 1 in 10 people):

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhoea, constipation, vomiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

Uncommon (may affect up to 1 in 100 people):

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion state
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding

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- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

Rare (may affect up to 1 in 1,000 people):

- Aggression, depersonalization (feelings of unreality and strangeness concerning oneself or the environment), hallucination (hearing voices or seeing things which are not there)
- Slow heart beat

Not known (frequency cannot be estimated from the available data):

- Thoughts of harming yourself or thoughts of killing yourself (see also subsection *Things to be careful of*)
- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Abnormal liver function test (increased amounts of liver enzymes in the blood)
- Movement disorders (involuntary movements of the muscles)
- Painful erections (priapism)
- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia)
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in men and in women that are not nursing
- Mania
- An increased risk of bone fractures has been observed in patients taking this type of medicines.

In addition, a number of side effects are known to occur with drugs that work in a similar way to escitalopram (the active ingredient of Lexapro). These are:

- Motor restlessness (akathisia)
- Anorexia

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→ Reporting).

Storage and Disposal of Lexapro

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month. Store below 25°C.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Lexapro is presented as 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets.

- 5 mg:** Round, white, film-coated tablets marked with “EK” on one side.
- 10 mg:** Oval, white, film-coated tablets. The tablets are scored and marked with “E” and “L” on each side of the score on one side of the tablet.
- 15 mg:** Oval, white, film-coated tablets. The tablets are scored and marked with “E” and “M” on each side of the score on one side of the tablet.
- 20 mg:** Oval, white, film-coated tablets. The tablets are scored and marked with “E” and “N” on each side of the score on one side of the tablet.

- Ingredients

- Active ingredient:

The active substance is escitalopram. Each Lexapro tablet contains 5 mg, 10 mg, 15 mg or 20 mg escitalopram (as oxalate).

- Inactive ingredient:

Core: microcrystalline cellulose, colloidal anhydrous silica, talc, croscarmellose sodium and magnesium stearate.

Coating: hypromellose, macrogol 400 and titanium dioxide (E-171)

- MAL No.:

5mg: MAL20041159A
10mg: MAL20041160A
15mg: MAL20041161A
20mg: MAL20041162A

Manufacturer

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Product Registration Holder

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