

Escitalopram-Apotex

escitalopram oxalate

5mg, 10mg and 20mg Film coated tablets

What is in this leaflet

Please read this leaflet carefully before you start using Escitalopram-Apotex.

This leaflet answers some common questions about Escitalopram-Apotex. 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 using Escitalopram-Apotex against the benefits they expect 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 Escitalopram-Apotex is used for

The name of your medicine is Escitalopram-Apotex tablet. It contains the active ingredient Escitalopram oxalate.

Escitalopram-Apotex 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.

Escitalopram-Apotex corrects this chemical imbalance and may help relieve the symptoms of depression.

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

Escitalopram-Apotex may also be used to treat patients who have excessive anxiety and worry.

Escitalopram-Apotex may also be used to treat 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 on-going need to repeat certain actions as a result of these thoughts.

Your doctor may have prescribed Escitalopram-Apotex for another reason.

Ask your doctor if you have any questions about why Escitalopram-Apotex has been prescribed for you.

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

Escitalopram-Apotex 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 Escitalopram-Apotex.

Before you use Escitalopram-Apotex

When you must not use it

Do not take ESCITALOPRAM-APOTEX if you are allergic to it, to any medicine containing 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 ESCITALOPRAM-APOTEX 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.

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

Taking Escitalopram-Apotex 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 Escitalopram-Apotex 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.

If you are not sure whether you should start using Escitalopram-Apotex, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- a tendency to bleed or bruise easily
- Diabetes
- heart disease, especially long QT syndrome or other conduction disorders
- conditions causing changes in the levels of sodium, potassium or magnesium in the blood (electrolytes)
- kidney disease
- liver disease
- bipolar disorder (manic depression)
- a history of seizures or fits
- Restlessness and/or a need to move often

3. You are currently pregnant or you plan to become pregnant.

Medicines like Escitalopram-Apotex have 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 with Escitalopram-Apotex.

Do not take Escitalopram-Apotex 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 Escitalopram-Apotex.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like Escitalopram-Apotex 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 Escitalopram-Apotex 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 Escitalopram-Apotex so they can advise you

If used during pregnancy Escitalopram-Apotex should never be stopped abruptly.

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

4. You are currently breastfeeding or you plan to breast-feed.

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

5. You are receiving electroconvulsive therapy.

If you have any of the above medical conditions, your doctor may perform additional tests, such as an ECG to check your heart and blood tests to check sodium, potassium and/or magnesium levels.

Do not give Escitalopram-Apotex to a child or adolescent.

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

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

The effects of Escitalopram-Apotex 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 start using Escitalopram-Apotex.

Medicines like Escitalopram -Apotex (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section Side Effects). In some cases, these symptoms have continued after stopping treatment.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Escitalopram-Apotex.

Some medicines may interfere with Escitalopram-Apotex. 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
 - mefloquine, an anti-malaria medicine
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- sumatriptan, used to treat migraines
 - tramadol, used to relieve pain
 - medicines affecting the chemicals in the brain
 - medicines that reduce the level of sodium, potassium or magnesium in the blood, e.g. diuretics ('fluid tablets')
 - some heart medications, e.g. flecainide, propafenone, metoprolol
 - Antiarrhythmic medicines, used to treat irregular heartbeats, e.g. amiodarone, disopyramide, Sotalol
 - Antifungal medicines e.g. fluconazole, voriconazole
 - Some antibiotics, e.g. azithromycin, clarithromycin, erythromycin, roxithromycin, amphotericin, gentamicin
 - Antihistamine medicines, used to relieve the symptoms of allergy (such as hay fever) or colds and 'flu, e.g. terfenadine, loratadine, Diphenhydramine
 - 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 premenstrual dysphoric disorder

These medicines may be affected by Escitalopram-Apotex, or may affect how well it works. You may need different amounts of your medicine, or you may need to 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.

Other medicines not listed above may also interact with escitalopram.

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

How to use Escitalopram-Apotex

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

The label should be carefully read

How much to take

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.

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

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet(s) whole with a full glass of water.

Do not chew them.

When to take it

Take Escitalopram-Apotex as a single dose either in the morning or in the evening.

Take Escitalopram-Apotex with or without food.

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it

Continue to take Escitalopram-Apotex 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 Escitalopram-Apotex. 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 Escitalopram-Apotex 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 Escitalopram-Apotex 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.

Your doctor will advise you when you can stop taking Escitalopram-Apotex completely.

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 missed doses.

This may increase the chance of you experiencing side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

While you are using Escitalopram-Apotex

Things you must do

Immediately stop taking Escitalopram-Apotex and check with your doctor if a skin rash or other allergic reaction occurs.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Escitalopram-Apotex.

Take your medicine exactly as your doctor has prescribed.

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

Tell your doctor (immediately) if you become pregnant while you are taking it.

Persons taking Escitalopram-Apotex may be more likely to think about killing themselves or actually trying to do so, especially when Escitalopram-Apotex 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 Escitalopram-Apotex 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 Escitalopram-Apotex. 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.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Escitalopram-Apotex.

Always discuss with your doctor any problems or difficulties during or after taking Escitalopram-Apotex.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Escitalopram-Apotex to last weekends and holidays.

Things you must not do

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

Do not take your medicine to treat any other condition unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Do not take any other medicine while you are taking Escitalopram-Apotex without first telling your doctor.

Do not take Escitalopram-Apotex for a longer time than your doctor has prescribed.

Suddenly stopping Escitalopram-Apotex may cause unwanted discontinuation symptoms such as dizziness, headache and nausea. Your doctor will tell you when and how Escitalopram-Apotex 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

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Escitalopram-Apotex 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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Escitalopram-Apotex.

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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Escitalopram-Apotex or if you have any questions or concerns.

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 adverse effects.

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

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 Escitalopram-Apotex are, in general, mild and disappear after a short period of time.

Tell your doctor if you notice any of the following:

- 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)

Tell your doctor immediately 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*
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) see Before you use Escitalopram-Apotex , Pregnancy section

These may be serious side effects of Escitalopram-Apotex. 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 hospitalization.

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 Escitalopram-Apotex.

If you or someone you know or care for experience any of the following, stop taking escitalopram and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Escitalopram-Apotex

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, 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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

Product description

What it looks like

Escitalopram-Apotex 5mg tablets are white to off white, circular, biconvex film coated tablets with 'C5' embossed on one side and plain on other side.

Escitalopram-Apotex 10mg tablets are white to off white, oval, biconvex film-coated tablets with 'C4' embossed on one side and notch break-line on other side.

Escitalopram-Apotex 20mg tablets are white to off white, oval, biconvex film-coated tablets with 'C3' embossed on one side and notch break-line on other side

Escitalopram-Apotex 5mg, 10mg and 20mg tablets are available in blister strips containing 14 tablets in packs of 14, 28, 56 or 98 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Active ingredient:

Each tablet contains 5mg, 10mg and 20mg of Escitalopram oxalate as the active ingredient.

Inactive ingredients:

- cellulose-microcrystalline
- silica-colloidal anhydrous
- talc-purified
- croscarmellose sodium
- magnesium stearate
- hypromellose
- macrogol 400
- titanium dioxide

Escitalopram-Apotex does not contain lactose, gluten, sucrose, tartrazine nor any other azo dyes.

Sponsor Details

Escitalopram-Apotex is supplied in New Zealand by:

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