Package leaflet: information for the user
Escitalopram 5 mg film-coated tablets
Escitalopram 10 mg film-coated tablets
Escitalopram 20 mg film-coated tablets
escitalopram

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Escitalopram film-coated tablets is and what it is used for

Escitalopram film-coated tablets contains the active substance escitalopram. Escitalopram film-coated tablets 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.

Escitalopram film-coated tablets contain escitalopram and are used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety disorder, generalised anxiety disorder and obsessive-compulsive disorder).

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram fil-coated tablets, even if it takes some time before you feel any improvement in your condition.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Escitalopram film-coated tablets

Do not take Escitalopram film-coated tablets

- If you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6)
- If you take other medicines, which belongs to a group, called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)

- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2"Other medicines and Escitalopram")

Warnings and Precautions

Talk to 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 Escitalopram film-coated tablets should be stopped if seizures occur for the first time or if there is an increase in the seizure frequency (see also section 4 "Possible 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 Escitalopram film-coated tablets 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 or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').
- If you are receiving electroconvulsive treatment.
- If you have coronary heart disease.
- If you suffer or have suffered from heart problems or have recently had a heart attack
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- If you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)

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.

Medicines like Escitalopram (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

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.

Use in children and adolescents

Escitalopram film-coated tablets 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 Escitalopram film-coated tablets for patients under 18 because he / she decide that this is in their best interest. If your doctor has prescribed Escitalopram film-coated tablets 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 Escitalopram film-coated tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Escitalopram film-coated tablets in this age group have not yet been demonstrated.

Other medicines and Escitalopram

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

Tell your doctor if you are taking any of the following medicines:

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing 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 Escitalopram film-coated tablets. After stopping Escitalopram film-coated tablets you must allow 7 days before taking any of these medicines.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
- "Irreversible MAO-B inhibitors" containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- Buprenorphine (a type of opioid medicine). Concomitant use increases the risk of serotonin syndrome, a potentially life-threatening condition. You may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol and similar medicines (opioids, used against severe pain). These increase the risk of side effects.
    - Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Escitalopram film-coated tablets.
- St. John's Wort (*hypericum perforatum*) - a herbal remedy used for depression.

- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anticoagulant). These may increase bleeding-tendency.
- Warfarin, dipyridamole and phenprocoumon (medicines used to thin the blood, so called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Escitalopram film-coated tablets in order to verify that your dose of anticoagulant is still adequate.
- 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 schizophrenia, psychosis) and antidepressants (tricyclic antidepressants and SSRIs) due to a possible risk of a lowered threshold for seizures, and antidepressants.
- Flecainide, propafenone and metoprolol (used in cardiovascular diseases); clomipramine and nortriptyline (antidepressants) and risperidone, thioridazine and haloperidol (antipsychotics). The dosage of Escitalopram Film-Coated Tablets may need to be adjusted.

DO NOT TAKE Escitalopram film-coated tablets if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (e.g. astemizole, hydroxyzine, mizolastine). If you have any further questions about this you should speak to your doctor.

Escitalopram film-coated tablets with food, drink and alcohol

Escitalopram film-coated tablets can be taken with or without food (see section 3 "How to take Escitalopram film-coated tablets").

As with many medicines, combining Escitalopram film-coated tablets with alcohol is not advisable, although Escitalopram film-coated tablets is not expected to interact with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not take Escitalopram film-coated tablets if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved. If you take Escitalopram film-coated tablets during the last 3 months of 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. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on Escitalopram film-coated tablets. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalopram film-coated tablets 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 midwife and/or doctor immediately.
If you take Escitalopram 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 so they can advise you.

If used during pregnancy Escitalopram film-coated tablets should never be stopped abruptly.

It is expected that escitalopram will be excreted into breast milk.

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.

Driving and using machines

You are advised not to drive a car or operate machinery until you know how Escitalopram film-coated tablets affects you.

Escitalopram tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Escitalopram film-coated tablets

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

Adults

Depression

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

Panic disorder

The starting dose of Escitalopram film-coated tablets 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 Escitalopram film-coated tablets 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 Escitalopram film-coated tablets 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 Escitalopram film-coated tablets 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)

The recommended starting dose of Escitalopram film-coated tablets is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Use in children and adolescents

Escitalopram film-coated tablets should not normally be given to children and adolescents. For further information please see section 2 “Warnings and precautions”.

Reduced kidney function
Caution is advised in patients with severely reduced renal function. Take as prescribed by your doctor.

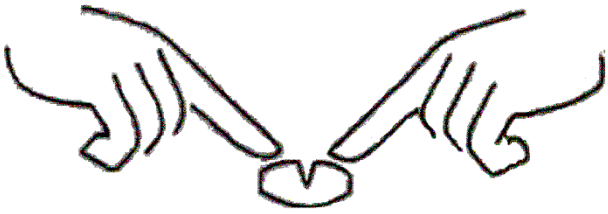
Reduced liver function
Patients with liver complaints should not receive more than 10 mg per day. Take as prescribed by your doctor.

Patients known to be poor metabolisers of the enzyme CYP2C19
Patients with this known genotype should not receive more than 10 mg per day. Take as prescribed by your doctor.

How to take tablets
You can take Escitalopram film-coated tablets with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

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.

Only 10 mg and 20 mg tablets can be divided into equal doses.



Duration of treatment

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram film-coated tablets even if it takes some time before you feel any improvement in your condition.

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

Continue to take Escitalopram film-coated tablets 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 take more Escitalopram film-coated tablets than you should

If you take more than the prescribed dose of Escitalopram film-coated tablets, 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,

coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid / salt balance. Take the Escitalopram Film-Coated Tablets box / container with you when you go to the doctor or hospital.

If you forget to take Escitalopram film-coated tablets

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 stop taking Escitalopram film-coated tablets

Do not stop taking Escitalopram film-coated tablets until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Escitalopram film-coated tablets is gradually reduced over a number of weeks.

When you stop taking Escitalopram film-coated tablets, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalopram film-coated tablets is stopped. The risk is higher, when Escitalopram film-coated tablets has been used for a long time or in high doses or when the dose is reduced too quickly. 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 Escitalopram film-coated tablets, 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).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible 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 any of the following symptoms 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 to1 in 1,000 people)

- Swelling of skin, tongue, lips, pharynx or face, hives or have difficulties breathing or swallowing (serious allergic reaction).
- High fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

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

- Difficulties urinating
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.
- Seizures (fits), see also section 2 “warning and precautions”
- Yellowing of the skin and the white in the eyes are signs of liver function impairment / hepatitis
- Thoughts of harming yourself or killing yourself, see also section 2 "Warnings and precautions"
- Sudden swelling of skin or mucosa (angioedemas)

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

Very common (may affect up to 1 in 10 people)

- Feeling sick (nausea)
- Headache

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
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

Rare (may affect up to 1 in 1000 people)

- Aggression, depersonalisation, hallucination
- Slow heart beat

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

- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Alteration of the heart rhrythm (called "pronlongation of QT interval", seen on ECG, electrical activity of the heart).
- 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)
- Signs of abnormal increased bleeding e.g from skin and mucous membranes (ecchymosis)
- Increased secretion of a hormone called ADH, causing the body to retain water and dilute the blood, reducing the amount of sodium (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
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more information

In addition, a number of side effects are known to occur with drugs that work in a similar way to Escitalopram Film-Coated Tablets (the active ingredient of Escitalopram). These are:

- Motor restlessness (akathisia)
- Loss of appetite

Reporting of side effects
If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie, e-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Escitalopram film-coated tablets

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 blister, label or carton after EXP.
The expiry date refers to the last day of that month.
Do not store above 30°C.
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.

6. Contents of the pack and other information

What Escitalopram film-coated tablets contains

The active substance is escitalopram.
Each Escitalopram 5mg film-coated tablet contains 5 mg escitalopram (as oxalate).

Each Escitalopram 10mg film-coated tablet contains 10 mg escitalopram (as oxalate).
Each Escitalopram 20mg film-coated tablet contains 20 mg escitalopram (as oxalate).

The other ingredients are:

Core: cellulose, microcrystalline (PH 101) (E460), croscarmellose sodium (E468), hypromellose E5 (E464), talc (E553b), colloidal anhydrous silica (E551), magnesium stearate (E470b)

Coating: hypromellose E-15 (E464), titanium dioxide (E171), macrogol 400

What Escitalopram film-coated tablets looks like and contents of the pack

Escitalopram film-coated tablets is presented as film-coated tablets. The tablets are described below.

5 mg: White to off-white, approximately 5.65mm in diameter, round, biconvex, film coated tablets plain on both side.
10 mg: White to off-white, oval, approximately 8.10mm in length, 5.60mm in width, biconvex film coated tablets with inscription '1' and '0' on either side of score line on one side and plain on other side.
20 mg: White to off-white, oval, approximately 11.60mm in length, 7.10mm in width, biconvex, film coated tablets with score line on one side and plain on other side.

The 10 mg and 20 mg tablets can be divided into equal doses.

Escitalopram film-coated tablets is available in the following pack sizes:

Blister(s) in outer carton:
5mg, 10mg and 20 mg: 14, 28, 56 and 98 tablets

HDPE bottle packs of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

United Kingdom

Ireland
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

Manufacturer

Accord Healthcare Limited,
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319, Pinner Road, North Harrow,
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Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	**Name of the medicinal product**
Austria	Escitalopram Accord 5 mg/10mg/20mg filmtabletten
Czech Republic	Escitalopram Accord 5 mg /10mg/20mg potahovaný tablety
Denmark	Escitalopram Accord Healthcare
Estonia	Escitalopram Accord 10mg/20mg
Ireland	Escitalopram 5 mg/10mg/20mg film-coated tablets
Latvia	Escitalopram Accord 10mg/20mg apvalkotās tabletes
Portugal	Escitalopram Accord
Spain	Escitalopram Accord 5 mg /10mg/20mg comprimidos recubiertos con pelнcula
Bulgaria	Escitalopram Accord 10 mg филмирани таблетки
Finland	Escitalopram Accord 10/20 mg Tabletti, kalvopäällysteinen
Italy	Escitalopram Accord
Netherland	Escitalopram Accord 5 mg/10 mg /20 mg Filmomhulde tabletten
Sweden	Escitalopram Accord 5 mg /10 mg /20 mg Filmdragerade tabletter
Slovakia	Escitalopram Accord 10 mg /20 mg filmom obalené tablety
United Kingdom	Escitalopram 5 mg/10 mg /20 mg Film-coated tablets

This leaflet was revised in 05-2023