

Package Leaflet: Information for the user  
**Escitalopram 10 mg Film-Coated Tablets**  
**Escitalopram 15 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.
- It may have some further questions and your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**What Escitalopram Tablets is and what it is used for**

- What you need to know before you take Escitalopram Tablets
- How to take Escitalopram Tablets
- Possible side effects
- How to store Escitalopram Tablets
- Contents of the pack and other information

**1. What Escitalopram Tablets is and what it is used for**

Escitalopram 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. Dysfunction in the serotonin system is considered an important factor in the development of depression and related diseases.

Escitalopram Tablets contains escitalopram and is used to treat depression (major depressive episode) and anxiety disorders such as panic disorder with or without agoraphobia, social anxiety disorder, generalized anxiety disorder and obsessive-compulsive disorder.

**2. What you need to know before you take Escitalopram Tablets**

**Do not take Escitalopram Tablets if you have:**

- any allergic (hypersensitive) reaction to escitalopram or any of the other ingredients of Escitalopram Tablets (see section 6).
- any use of other medicines that belong to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and fluoxetine (antidepressant).
- if you are born with or have had an episode of abnormal heart rhythm (see at ECG, an examination) or have had the heart blocked.
- if you are taking medicines for heart rhythm problems or that may affect the heart rhythm (see section 2).

**Warnings and precautions**

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 Escitalopram Tablets should be stopped if seizures occur in the first 10 days of therapy or increase in the seizure frequency (see section 4).
- if you have thyroid disease. Treatment with Escitalopram Tablets may alter thyroxine levels and your thyroid gland may need to be adjusted.
- if you have a known or suspected risk of bleeding.
- if you have a tendency to easily develop bleeding or bruising.
- if you are taking or recently took blood thinning treatment.
- if you are on any other heart disease treatment.
- if you have a low weight, heart-rate and/or you know that you may have salt depletion as a result of prolonged vomiting and/or watery stools (see section 4) or use of diuretics (water tablets).
- if you experience a fast, irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- if you suffer from angle-closure glaucoma or have a history of glaucoma.

**Pregnancy and breastfeeding**

Some patients with major depressive illness may enter into a manic phase. This is characterized by unusual and rapid changing ideas, inappropriate behavior and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty in sitting or standing 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 also have a stimulating effect on the brain.

You may be more likely to think this if:

- 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 behavior 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 hospital straight away. In the worst case, inform the police.

You should tell them your doctor or if symptoms have become worse or if you are worried about your safety.

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 keeping you safe.

**Children and adolescents**

Escitalopram 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 thoughts, suicidal thoughts and hostility (pronouncedly aggressive, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Escitalopram Tablets for patients under 18 because they believe that this is in their best interest. If your doctor has prescribed Escitalopram Tablets for a patient under 18 and you want to discuss this, please go back to your doctor. You should tell them your doctor or if symptoms have become worse or if you are worried about your safety.

Some patients who are taking Escitalopram Tablets. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Escitalopram Tablets in this age group have not yet been demonstrated.

**Other medicines and Escitalopram Tablets**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

**Do not drink alcohol** while taking any of the following medicines:

- Non-steroidal anti-inflammatory drugs (NSAIDs) containing phenazone, ibuprofen, ibuprofen, acetaminophen.

naloxone, and tramypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Escitalopram Tablets. After stopping Escitalopram Tablets, you must wait 14 days before taking any of these medicines.

- Tramadol, which is a MAO-A inhibitor, containing meprobamate (used to treat depression).
- Tramadol MAO-B inhibitor, containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- The antibiotic levofloxacin.
- Chlorzoxazone (a painkiller of narcotic depressant disorder) and tramadol.
- Insipirone and desipirone (both used to treat depression).
- Contraception and/or medicines (used to treat gonorrhoea) and tamoxifen (used against some pain). These increase the risk of side effects.
- Chemicals and minerals (used to treat stomach ulcers), Risperidone (antidepressant) and isotopine (used to reduce the risk of stroke). These may cause increased blood levels of Escitalopram Tablets.
- St. John's wort (hypericum perforatum), a herbal remedy used for depression.
- Acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood in so-called anticoagulants). These may increase bleeding tendency.
- Warfarin, glycyrrhizic acid 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 Tablets in order to verify that your dose of anticoagulant is adequate.
- Medicines used to treat malaria, kanirocin (used to treat depression) and tramadol (used to treat severe pain) as possible risk of a lowered threshold for seizure.
- Medicines used to treat schizophrenia, psychosis due to a possible use of a lowered threshold for seizure, and antidepressants.
- Medicines used to treat schizophrenia, psychosis due to a possible use of a lowered threshold for seizure, and antidepressants.
- Neuroleptics, propofol and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants) and ropivacaine, bupivacaine, and local anesthetic (anesthetics). The change of Escitalopram Tablets may need to be reduced.
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of the bradycardia heart rhythm disorder.

Do not take Escitalopram Tablets if you take medicines for heart rhythm problems or medicines that may affect the heart rhythm, such as Class I and II antiarrhythmic, antianginal (e.g. phenothiazine derivatives, imidazole, benzimidazole, triptyc antidepressants, certain antidepressants (e.g. sertraline, moclobemide, erythromycin), pentamidine, anti-malaria treatment (parafolinate, chloroquine, quinine), certain anti-infectives (e.g. azolemic, miconazole).

If you have any further questions describe you should speak your doctor.

**Escitalopram Tablets with food, drink and alcohol**

Escitalopram Tablets can be taken with or without food (see section 3 'How to take Escitalopram Tablets').

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

**Pregnancy, breast-feeding and fertility**

Inform your doctor if you are pregnant or planning to become pregnant. Do not take Escitalopram Tablets if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.

**If you take Escitalopram 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, skull size, the body temperature change, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, viral infections, pneumonia, irritability, seizures, constant crying, depression 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. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalopram Tablets may increase the risk of a serious condition in babies called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe in the best possible way. These symptoms usually begin during the 24 hours after the baby is born. If this happens to your baby, please contact your midwife and/or doctor immediately.

Escitalopram Tablets should never be stopped abruptly.

Combining a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Therefore, this could affect fertility, but impact on human fertility has not been observed yet.

**Driving and using machines**

You should not drive a car or operate machinery until you know how Escitalopram Tablets affects you.

**How to take Escitalopram Tablets**

Always take Escitalopram Tablets exactly as your doctor has told you. Check your doctor or pharmacist if you are not sure.

**Adults**

Depression

The normally recommended dose of Escitalopram 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 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 Tablets is 10 mg taken as one daily dose. Your doctor can further increase your dose to a maximum of 20 mg per day if necessary. 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 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 Tablets is 5 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

**Children and adolescents (below 18 years of age)**

Escitalopram Tablets should not normally be given to children and adolescents. For further information please see section 2.

**You can take Escitalopram Tablets with or without food.** Swallow the tablet with some water. Do not chew them, as this risks blockage.

If necessary, the tablets can be divided into equal halves.

**Duration of treatment**

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram 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 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 Tablets than you should**

If you take more than the prescribed dose of Escitalopram 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, vertigo, agitation, confusion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid balance. Take the Escitalopram Tablets box/containers with you when you go to the doctor or hospital.

**If you forget to take Escitalopram 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 are taking Escitalopram Tablets**

Do not stop taking Escitalopram 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 Tablets is gradually reduced over a number of weeks.

When you stop taking Escitalopram Tablets, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalopram Tablets is stopped. The risk is higher when Escitalopram Tablets has been used for a long time or at 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 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 (vertigo) or off-balance, feeling the pins and needles, burning sensation (less commonly electric shock sensation), itching in the head, sleep disturbances (insomnia), diarrhoea, fatigue, feeling tired, feeling anxious, headache, feeling hot or cold, weight gain (possibly not related to diet), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling nervous or irritable, diarrhoea (loose stools), sexual dysfunction, fading or pouring of heart rate (palpitations).

**Interactions**

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

**Side effects**

Like most medicines, Escitalopram Tablets 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.

**See your doctor if you get any of the following side effects during treatment:**

**Common (affects 1 to 10 users in 1000)**

- Unusual bleeds, including gastrointestinal bleeding.

**Uncommon (affects 1 to 10 users in 10000)**

- Unusual bleeds, including gastrointestinal bleeding.
- If you experience swelling of skin, tongue, lips, or face, or have difficulty breathing or swallowing (allergies), contact your doctor or go to hospital straight away.
- If you have a high fever, agitation, confusion, trembling and rapid contractions of muscles these may be signs of a rare condition called serotonin syndrome. If you notice this, contact your doctor.

**Rare (affects 1 to 10 users in 100000)**

- Difficulty swallowing.
- Sudden (fit), see also section 'See special care instructions with Escitalopram Tablets'.
- Narrowing of the airway and/or in the eye or in the eye after further impairment happens.
- Fast, irregular heart beat, feeling which could be symptoms of a life-threatening condition known as torsades de pointes.

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

**Very common (affects more than 1 user in 10):**

- Fatigue or tiredness.
- Headache.

**Common (affects 1 to 10 users in 1000):**

- Blocked or runny nose (nasitis).
- Dizziness or lightheadedness.
- Anxiety, restlessness, abnormal dreams, feelings falling asleep, feeling sleepy, dizziness, yawning, tremors, pruritus (itch),
- Dryness in mouth, constipation, vomiting and dry mouth.
- Increased sweating.
- Pain in muscles (myalgia), back pain and myalgia.
- Decreased weight.
- Sexual dysfunction (decreased libido, problems with erection, decreased sexual drive and women may experience difficulty achieving orgasm).
- Fatigue.
- Increased weight.

**Uncommon (affects 1 to 10 users in 10000):**

- Nausea and vomiting (with or without blood).
- Cramping or pain in the stomach, pain in the back, constipation.
- Difficulty sleeping (insomnia), decreased energy (asthenia).
- Enlargement of spleen (splenomegaly), sexual disturbance, tingling in the ears (tinnitus).
- Loss of hair.
- High blood pressure.
- Decreased weight.
- Fatigue.
- Swelling of the legs or arms.
- Nosebleeds.

**Rare (affects 1 to 10 users in 10000):**

- Aggression, depression, suicidal thoughts.
- Slow heartbeat.

precursor'. Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or cramps).

- 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).
- Fatigue and/or insomnia.
- Bleeding disorders including skin and mucosa bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia).
- Swollen swelling of skin or mucosa (angioedema).
- Increases the amount of urine excreted (natriuresis/ACh secretions).
- Flow of milk in women that are not nursing.
- Male.
- An increased risk of arrhythmias has been observed in patients taking this type of medicine.
- Alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, measuring electrical activity of the heart).

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 Escitalopram Tablets. These are:

- Major restlessness (akathisia).
- Anxiety.

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

**How to store Escitalopram Tablets**

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

Special storage conditions:  
Blister pack: Store at or below 30°C.

Escitalopram Tablets do not require any special storage conditions.

Do not use Escitalopram Tablets 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.

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.

**Contents of the pack and other information**

**What Escitalopram Tablets contains**

The active ingredient is escitalopram.  
Each Escitalopram tablet contains either 10 mg, 15 mg or 20 mg escitalopram (as oxalate).

The other ingredients are:  
Core: Dibutyltin-divinyltoluene-carboxylic acid, croscarmellose sodium, talc and magnesium stearate.  
Coating: Hydroxypropylmethylcellulose E-50, Titanium Dioxide (E171) and Polyethylene glycol 6000.

**What Escitalopram Tablets looks like and contents of the pack**

Escitalopram is presented as 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets. The tablets are described below.

5 mg: White to off-white, circular, biconvex, film-coated tablets plain on both faces.

10 mg: White to off-white, capsule shaped, biconvex, film-coated tablets engraved with 10 on one face and a score line on the other face.

15 mg: White to off-white, capsule shaped, biconvex, film-coated tablets engraved with 15 on one face and a score line on the other face.

20 mg: White to off-white, capsule shaped, biconvex, film-coated tablets engraved with 20 on one face and a score line on the other face.

Escitalopram Tablets are packaged in PVC/PPE/Aluminum blisters containing 7, 10, 14, 20, 28, 40, 49, 56, 98, 100, 120 Tablets and/or blister packs with Polypropylene cap containing 10, 20, 30, 40, 50, 98, 100, 120 tablets may be available.

**Marketing Authorisation Holder and Manufacturer**

Brown & Burk LLC  
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United Kingdom.

**This medicinal product is authorised in the Member States of the EE under the following names**

PT: Escitalopram Brown 5 mg 10 mg 15 mg 20 mg compressed round/oval/pellicular  
DE: Escitalopram-MacL 5 mg 10 mg 15 mg 20 mg Tabletten  
FR: Escitalopram B&B 5 mg 10 mg 15 mg 20 mg comprimés  
Escitalopram Brown & Burk 10 mg 15 mg 20 mg comprimés pelliculaires

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