Package Leaflet: Information for the user

Escitalopram 5 mg Film-Coated Tablets
Escitalopram 10 mg Film-Coated Tablets
Escitalopram 15 mg Film-Coated Tablets
Escitalopram 20 mg Film-Coated Tablets

(escitalopram)

BROWN & BURK

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. 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.

In this leaflet:

1. What Escitalopram Tablets is and what it is used for
2. What you need to know before you take Escitalopram Tablets
3. How to take Escitalopram Tablets
4. Possible side effects
5. How to store Escitalopram Tablets
6. 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. Disturbances in the serotonin - system are considered an important factor in the development of depression and related diseases.

Escitalopram Tablets contains escitalopram and is 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).

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

Do not take Escitalopram Tablets

- If you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Escitalopram Tablets (see section 6).
- If you take other medicines that 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)

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 Tablets should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency (see section 4).
- If you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- If you have diabetes. Treatment with Escitalopram 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.
- 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 suffer from angle-closure glaucoma or have a history of glaucoma.

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 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 yourselves. 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 a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorders, 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.

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 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 Tablets for patients under 18 because he/she decides 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 inform your doctor if any symptoms listed above develop or worsen when patients under 18 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.

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 Tablets. After stopping Escitalopram 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.
- 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 (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 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, so called anti-coagulant). These may increase bleeding tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anti-coagulants). 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 anti-coagulant is still adequate.
- Mefloquine (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) 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 Tablets may need to be adjusted.
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder.

Do not take Escitalopram 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, mizolastine).
If you have any further questions about this you should speak to 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, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremors, jittariness 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. 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 to be faster 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 used during pregnancy Escitalopram Tablets should never be stopped abruptly.

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.

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.

Driving and using machines
You are advised not to drive a car or operate machinery until you know how Escitalopram Tablets affects you.

3. How to take Escitalopram Tablets

Always take Escitalopram Tablets exactly as your doctor has told you. Check with 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 doses 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 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 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 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 10 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 the taste is bitter.

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, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid / salt balance. Take the Escitalopram Tablets box/container 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 stop 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 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 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.

4. Possible side effects

Like all medicines, Escitalopram Tablets can cause side effects, although not everybody gets them.

The side effects usually disappear after a few weeks of treatment. Please beware 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:

Uncommon (affects 1 to 10 users in 1000):
- Unusual bleeds, including gastrointestinal bleeding

Rare (affects 1 to 10 users in 10000):
- 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.

If you experience the following side effects you should contact your doctor or go to the hospital straight away.
- Difficulties urinating
- Seizures (fits), see also section "Take special care with Escitalopram Tablets"
- Yellowing of the skin and white in the eyes are signs of liver funtion impairment/ hepatitis.
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as **torsade de pointes**.

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

Very common (affects more than 1 user in 10):
- Feeling sick (nausea)
- Headache

Common (affects 1 to 10 users in 100):
- 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 and 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 (affects 1 to 10 users in 1000):
- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attacks, confusion state
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Vaginal bleeding
- Decreased weight
- Fast heartbeat
- Swelling of the arms or legs
- Nosebleeds

Rare (affects 1 to 10 users in 10000):
- Aggression, depersonalisation, hallucination
- Slow heartbeat

Some patients have reported (frequency can not be estimated from the available data):
- Thoughts of harming yourself or thoughts of killing yourself, see also section "Warnings and precautions" 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 women that are not nursing
- Mania
- An increased risk of bone fractures 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 similar way to escitalopram (the active ingredient of Escitalopram Tablets). 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.

5. How to store Escitalopram Tablets

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

Special storage conditions:
Blister pack: Do not store above 30° C
Container pack: This medicinal product does 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 to protect the environment.

6. Contents of the pack and other information

What Escitalopram Tablets contains

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

The other ingredients are:
Core: Silicified Microcrystalline cellulose, croscarmellose sodium, talc and magnesium stearate.

Coating: Hydroxypropylmethyl cellulose 6 cps, 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 break line on the other face.
15 mg: White to off-white, capsule shaped, biconvex, film-coated tablets engraved with 15 on one face and break line on the other face.
20mg: White to off-white, capsule shaped, biconvex, film-coated tablets engraved with 20 on one face and break line on the other face.

Escitalopram Tablets are packaged in PVC/PE/PVdC-Aluminium blisters containing 7, 10, 14, 20, 28, 49, 50, 56, 98, 100 or 500 Tablets and HDPE bottles with Polypropylene cap containing 30, 60, 100, 200 or 500 Tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
United Kingdom.

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

PT: Escitalopram Brown 5 mg/10 mg/15 mg/20 mg comprimidos revestidos por película
UK: Escitalopram 5 mg/10 mg/15 mg/20 mg Film-Coated Tablets
DE: Escitalopram Micro Labs 5 mg/10 mg/15 mg/20 mg Filmtabletten
FR: Escitalopram Brown & Burk 5 mg comprimé pelliculé
Escitalopram Brown & Burk 10 mg/15 mg/20 mg comprimé pelliculé sécable

This leaflet was last approved in 10/2013

PL0030AB UKI-026/B