

PACKAGE LEAFLET: INFORMATION FOR THE USER

Escitalopram BioOrganics 10 mg film-coated tablets
Escitalopram BioOrganics 15 mg film-coated tablets
Escitalopram BioOrganics 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Escitalopram BioOrganics is and what it is used for
2. What you need to know before you take Escitalopram BioOrganics
3. How to take Escitalopram BioOrganics
4. Possible side effects
5. How to store Escitalopram BioOrganics
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1. What Escitalopram BioOrganics 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 BioOrganics contains escitalopram and is used to treat depression (major depressive episodes) and anxiety disorders such as repeated panic attacks (panic disorder) with or without fear of experiencing a panic attack in a place or situation from which escape is difficult or embarrassing e.g. in public or open spaces (agoraphobia), fear of being judged by others and/or publicly behaving in a way that could lead to embarrassment (social anxiety disorder), chronic anxiety (generalised anxiety disorder) and obsessions or compulsions that interfere with normal life functioning for example, repeatedly washing hands or checking locks (obsessive-compulsive disorder).

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

Do not take Escitalopram BioOrganics

- if you are **allergic to escitalopram or any of the other ingredients** of this medicine (listed in section 6).

- if you are taking other medicines which belong to a group called monoamine oxidase inhibitors (**MAOIs**), **including medicines to treat depression** (moclobemide), **a medicine to treat Parkinson's disease (selegiline)** and an **antibiotic** (linezolid).
- 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 BioOrganics*").

Warnings and precautions

Talk to your doctor or pharmacist before taking Escitotab.

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

- suffer from repeated **panic attacks** (panic disorder). You may experience increased anxiety symptoms at the beginning of the treatment with escitalopram.
- have **epilepsy** or have had **seizures or fits** in the past. Treatment with escitalopram should be stopped if seizures occur or if there is an increase in the seizure frequency (see section 4, Possible side effects).
- have had **episodes of rapidly changing ideas, exaggerated moods or behaviour (mania)**.
- have **diabetes**. Treatment with escitalopram may alter your blood sugar level. Your dosage of insulin and/or oral antidiabetic medicines may need to be adjusted.
- suffer from unpleasant or distressing **restlessness**, need to move often or are unable to sit or stand still.
- If you have a **decreased level of sodium in the blood**.
- if you suffer from **impaired liver or kidney function**. Your doctor may need to adjust your dosage.
- if you have a history of **bleeding or bruising disorders**, particularly if you are taking **medicines that cause an increased risk of bleeding**.
- are receiving electroconvulsive therapy (**ECT**).
- are taking herbal remedies containing **St. John's Wort**.
- 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, it may indicate **abnormal functioning of the heart**.
- if you have **angle-closure glaucoma or have had glaucoma** as escitotab may increase intraocular pressure

Please note

As with other medicines used to treat depression, the improvement is not achieved immediately. After the start of escitalopram-treatment it may take several weeks before you experience any improvement. Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor.

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 disorder is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents under 18 years of age

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

Other medicines and Escitalopram BioOrganics

Other medicines may be affected by escitalopram. They, in turn, may affect how well escitalopram works.

Escitalopram can interact with:

- **non-selective monoamine oxidase inhibitors (MAOIs)** like phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine (and used to treat e.g. depression). If you have taken any of these medicines you will need to wait 14 days before you start taking escitalopram. After stopping escitalopram you must allow 7 days before taking any of these medicines.
- reversible, selective MAO-A inhibitors, e.g. **moclobemide** (used to treat depression).
- **linezolid**, an antibiotic.
- **selegiline**, used to treat Parkinson's disease. The risk of side effects is increased.
- **tramadol** (a pain killer), and medicines called triptans, such as sumatriptan (used to treat **migraine**). These increase the risk of side effects.
- medicines to treat schizophrenia, psychosis (neuroleptics), other antidepressants, tramadol (a **pain killer**), bupropion (used to help people **stop smoking**), and

mefloquine (used for the treatment and prevention of **malaria**) - due to a possible risk of a lowered threshold for seizures.

- **tryptophan** (a dietary supplement which is converted to serotonin during metabolism) and lithium (used to treat **psychiatric conditions**).
- Herbal remedies containing **St. John's Wort** (for the treatment of depression).
- acetylsalicylic acid, ibuprofen or other medicines called **NSAIDs** (non-steroidal anti-inflammatory drugs) for the relief of **pain and inflammation** as bleeding tendency may increase.
- warfarin, dipyridole or other medicines (called anticoagulants) **used to thin the blood**. Your doctor will probably check the coagulation time of your blood when starting and discontinuing escitalopram in order to verify that your dose of anti-coagulant is still adequate.
- cimetidine, omeprazole, esomeprazole and lansoprazole (used to treat **stomach ulcers**), fluvoxamine (antidepressant), ticlopidine (used to **reduce the risk of stroke**). Your dose of escitalopram might need to be reduced.
- medicines inducing loss of potassium and magnesium like certain diuretics used for instance to control **hypertension**.
- flecainide, propafenone and metoprolol (used to treat **heart problems**), clomipramine, nortriptyline and desipramine (antidepressants) and risperidone, thioridazine or haloperidol (used to treat **psychiatric conditions**). Your dosage might need to be adjusted.

DO NOT TAKE Escitalopram BioOrganics 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-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

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

Escitalopram BioOrganics with food, drink and alcohol

Escitalopram can be taken with or without food. You should not drink **alcohol** while you are taking escitalopram as your symptoms or side effects might get worse.

Pregnancy, breast-feeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 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.

You should not discontinue treatment with escitalopram abruptly. If you are taking escitalopram in the last 3 months of pregnancy, let your doctor know as your baby might have some symptoms when it is born. These symptoms usually begin during the first 24 hours after the baby is born. They might include not being able to sleep or feed properly, sleepiness, trouble with breathing, a blu-ish skin or being too hot or cold, crying a lot, vomiting, low blood sugar, stiff or floppy muscles, irritability, lethargy, tremors, vivid reflexes, jitters or fits. If your baby has any of these symptoms when it is born, **talk to your doctor** immediately who will be able to advise you.

Breast-feeding

Escitalopram is likely to pass into breast milk. Do not take escitalopram if you are breast-feeding unless you and your doctor have discussed the risks and benefits involved.

Fertility

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 affects you. Escitalopram can cause **dizziness, tiredness, confusion or hallucinations (strange visions or sounds)**. If you have any of these side-effects, do not drive or use machinery.

3. How to take Escitalopram BioOrganics

Always take this medicine exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure. It might be several weeks before you start to feel better. **Do not stop taking your medicine or change your dose without talking to your doctor first.** You should keep taking your tablets for as long as your doctor tells you to, even if you start to feel better. If you don't start to feel better after a couple of weeks, go back to your doctor. He/she may decide to increase your dose gradually, up to the maximum daily dose of 20 mg. The safety of daily doses above 20 mg has not been shown.

The usual dose of escitalopram is given below. Your doctor will tell you how long you need to take your tablets for. This could be several months or longer.

You can take your tablets with or without food. **Take your medicine once a day.** Swallow the tablets with water. The tablet can be divided into equal doses. Do not chew them.

Adults

The usual daily dose for the treatment of **depression, generalised anxiety disorder or obsessive compulsive disorder** is 10 mg.

For the treatment of **panic disorder and social phobia** (social anxiety disorders), your doctor may decide to give you a lower dose (5 mg daily). Your doctor may increase your dose up to a maximum of 20 mg.

Elderly patients(above 65 years of age)

The recommended starting dose of Escitalopram BioOrganics 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 should not be used in the treatment of children and adolescents under the age of 18 years (see section 2, Use in children and adolescents under 18 years of age).

Patients with liver disease

If you have liver disease, your doctor might decide escitalopram to give you a lower dose of 5 mg a day during the first 2 weeks of treatment. Your doctor may increase your dose to 10 mg daily.

Patients with kidney disease

If you suffer from severe kidney disease use of escitalopram is not recommended. If you have mild or moderate kidney disease, you can use the normal dose of escitalopram.

If you take more Escitalopram BioOrganics than you should

Never take more tablets than your doctor tells you to. If you think that you, or someone else, may have taken too much escitalopram, **contact your doctor or hospital straight away**. Do this even if there are no signs of discomfort. Symptoms of overdose might include dizziness, shaking, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the escitalopram carton with you.

If you forget to take Escitalopram BioOrganics

If you forget to take your tablet, take the next tablet at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Escitalopram BioOrganics

Do not stop taking escitalopram until your doctor tells you to. When stopping treatment with escitalopram, your doctor will gradually reduce your dose over a number of weeks or months. This should help reduce the possibility of withdrawal effects. If you do experience withdrawal effects when stopping treatment with escitalopram, your doctor might decide that you need to reduce your dose more slowly. If your withdrawal effects are severe, go back and talk to your doctor.

Most people find that withdrawal effects are mild and go away on their own within 2 weeks; however, they can sometimes be severe and/or prolonged.

Possible withdrawal effects when stopping treatment might include dizziness, sleep disturbance, anxiety, shaking, feeling sick, headache, confusion, agitation, sensory disturbances (e.g. tingling, pricking or numbness of skin, hallucinations), dreaming, sweating, diarrhoea, feeling emotional or irritable and irregular heart rate.

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

4. Possible side effect

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

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

Uncommon (affects 1 to 10 users in 1,000)

Unusual bleeds, including gastrointestinal bleeds

Rare (affects 1 to 10 users in 10,000)

Allergic reactions such as skin rash, swelling of the face, eyelids, mouth or tongue and difficulty breathing or swallowing.

If you have any of the following symptoms, you might have serotonin syndrome: high fever, agitation, confusion, trembling and abrupt contractions of muscles

Unknown (frequency cannot be estimated from the available data)

Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Other side effect can be

Very common (affects more than 1 user in 10)

Feeling sick, headache

Common (affects 1 to 10 users in 100)

Weight gain • Change in sex drive • Change in sexual function (for example, in men, erection or ejaculation problems, and in women, lack of orgasm) • Feeling anxious • Restlessness • Disturbed sleep (including abnormal dreaming) • Not sleeping well (insomnia) • Feeling sleepy • Yawning • Feeling dizzy or shaky • Loss of appetite (anorexia) or increased appetite • Tingling or pins and needles like sensations • Blocked or running nose (sinusitis) • Feeling tired • Fever • Dry mouth • Increased sweating • Diarrhoea • Constipation • Muscle ache • Pains in the joints • Vomiting

Uncommon (affects 1 to 10 users in 1,000)

Weight loss • Skin rashes or itching • Altered taste • Sleep problems • Hair loss • Panic attacks • Grinding or clenching teeth • Feeling confused • Buzzing, thumping or tingling sound in the ears (tinnitus) • Fast heartbeat • Abnormal vision • Passing blood

in your stools • Bleeding from the nose or vagina • Abnormal heavy bleeding at menstruation • Fluid retention in the body (oedema) • Agitation • Nervousness • Fainting (syncope) • Enlarged pupils (mydriasis)

Rare (affects 1 to 10 users in 10,000)

Slow heartbeat • Aggression • Feeling unreal or detached from your body (depersonalization) • Strange visions or sounds (hallucination).

Some patients have reported (frequency cannot be estimated from the available data): Episodes of rapidly changing ideas, exaggerated moods or behaviour (mania), abnormal quantities of breast-milk produced, or flow of breast-milk after breast-feeding has stopped, motor restlessness (akathisia) • Convulsions • Movement disorder, involuntary movements • Low levels of sodium in the blood with or without water retention which may cause swelling of the arms or legs (swelling up) (the symptoms are feeling sick or unwell with aching, weak muscles and feeling confused) • Difficulty passing water (urinating) or passing large amounts of urine • Dizziness when you stand up due to low blood pressure (orthostatic hypotension) • 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 (SIADH) • Liver inflammation (hepatitis) including yellowing of the skin and the white in the eyes • Alteration of the heart rhythm (ventricular arrhythmia) or condition called “prolongation of QT interval”, seen on ECG, what may increase risk of heart rate alterations).

Cases of thoughts/behaviours of harming or killing yourself have been reported during escitalopram therapy or early after treatment has been stopped (see section 2, Take special care with Escitalopram BioOrganics).

An increased risk of bone fractures has been observed in patients taking this type of medicines.

Reporting 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 [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Escitalopram BioOrganics

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

Do not use this medicine after the expiry date stated on the blister and carton after ‘EXP’. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

This medicine does not require any special storage condition.

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 BioOrganics contains

- The active substance is escitalopram.
Each 10 mg tablet contains escitalopram oxalate equivalent to 10 mg escitalopram.
Each 15 mg tablet contains escitalopram oxalate equivalent to 15 mg escitalopram.
Each 20 mg tablet contains escitalopram oxalate equivalent to 20 mg escitalopram.
- The other ingredients in the tablet core are: microcrystalline cellulose, colloidal anhydrous silica, talc, croscarmellose sodium and magnesium stearate
The ingredients in the tablet coating are: hypromellose, macrogol 400 and titanium dioxide (E 171)

What Escitalopram BioOrganics 10 mg looks like and contents of the pack

Escitalopram BioOrganics 10 mg is a white, oval, film-coated tablet, debossed with 'E9CM' on one side and on the other side scored and debossed with '10' (one number on each side of the scoring line).

Eschiton 10 mg is available in blister in a cardboard box containing 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 or 200 tablets.

What Escitalopram BioOrganics 15 mg looks like and contents of the pack

White, oval, film-coated tablets, debossed with 'E9CM' on one side and on the other side scored and debossed with '15' (one number on each side of the scoring line).

Escitalopram BioOrganics 15 mg is available in blister in a cardboard box containing 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 or 200 tablets.

What Escitalopram BioOrganics 20 mg looks like and contents of the pack

White, oval, film-coated tablets, debossed with 'E9CM' on one side and on the other side scored and debossed with '20' (one number on each side of the scoring line).

Escitalopram BioOrganics 20 mg is available in blister in a cardboard box containing 5, 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 or 200 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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PA1082/002/001; Escitalopram BioOrganics 10 mg
PA1082/002/002; Escitalopram BioOrganics 15 mg
PA1082/002/003; Escitalopram BioOrganics 20 mg

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

Ireland	Escitalopram BioOrganics
Portugal	Escitalopram BioOrganics
Spain	Escitalopram BioOrganics, comprimidos EFG

This leaflet was last approved in { dd/mm/yyyy }