Package leaflet: Information for the patient

Escitalopram Krka 5 mg film-coated tablets
Escitalopram Krka 10 mg film-coated tablets
Escitalopram Krka 15 mg film-coated tablets
Escitalopram Krka 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 Krka is and what it is used for

Escitalopram Krka contains the active substance escitalopram. Escitalopram belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs).

Escitalopram Krka 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).

It may take a couple of weeks before you start to feel better. Continue to take Escitalopram Krka, 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 Krka

Do not take Escitalopram Krka
- 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 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 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 Krka").

Warnings and precautions
Talk to your doctor or pharmacist before taking Escitalopram Krka.

Please 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 Krka 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 Krka 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 or have previously had 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 characterised 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 Krka (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.
Children and adolescents
Escitalopram Krka 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 Krka for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Escitalopram Krka 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 Krka. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Escitalopram Krka in this age group have not yet been demonstrated.

Other medicines and Escitalopram Krka
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)” (used to treat depression), 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 Krka. After stopping Escitalopram Krka 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 (used to treat depression).
- 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.
- 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 anti-coagulant). These may increase bleeding tendency.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anti-coagulant). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Escitalopram Krka in order to verify that your dose of anti-coagulant 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.
- Flecainide, propafenone, and metoprolol (used in cardio-vascular diseases), clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Escitalopram Krka 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 Krka 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, hydroxyzine, mizolastine). If you have any further questions about this you should speak to your doctor.

Escitalopram Krka with food, drink and alcohol
Escitalopram Krka can be taken with or without food (see section 3 “How to take Escitalopram Krka”).

As with many medicines, combining Escitalopram Krka with alcohol is not advisable, although

escitalopram 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 Krka if you are pregnant or breast-feeding unless you and your doctor have discussed the risks and benefits involved.

If you take Escitalopram Krka 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 Krka. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalopram Krka 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 Krka 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 Krka so they can advise you.

If used during pregnancy Escitalopram Krka 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
Do not drive a car or operate machinery until you know how Escitalopram Krka affects you.

Escitalopram Krka contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Escitalopram Krka

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

Route and method of administration
You can take Escitalopram Krka with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.
10 mg and 20 mg tablet: The tablet 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 Krka 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 Krka 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 Krka than you should
If you take more than the prescribed dose of Escitalopram Krka, 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 Krka box with you when you go to the doctor or hospital.

If you forget to take Escitalopram Krka

Do not take a double dose to make up for a forgotten dose. If you do forget to take a dose, and you remember it 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 Krka
Do not stop taking Escitalopram Krka 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 Krka is gradually reduced over a number of weeks.

When you stop taking Escitalopram Krka, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalopram Krka is stopped. The risk is higher, when Escitalopram Krka 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 Krka, 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, 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 to 1 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.
- Seizures (fits), see also section Warnings and precautions.
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis.
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as *Torsade de Pointes*.
- Thoughts of harming yourself or killing yourself, see also section “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 more than 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 state
- 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 1,000 people):
- Aggression, depersonalisation, hallucination
- Slow heart beat

Not known (frequency cannot be estimated from available data):
- 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)
- Signs of abnormal bleeding e.g. from skin and mucous (ecchymosis) and low level of blood platelets (thrombocytopenia)
- 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)
- Increased blood levels of the hormone prolactin
- 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
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)
- 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 (the active ingredient of Escitalopram Krka). 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Escitalopram Krka

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 packaging. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

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 Krka contains
- The active substance is escitalopram.
  Each film-coated tablet contains 5 mg escitalopram corresponding to 6.390 mg escitalopram oxalate.
  Each film-coated tablet contains 10 mg escitalopram corresponding to 12.780 mg escitalopram oxalate.
  Each film-coated tablet contains 15 mg escitalopram corresponding to 19.170 mg escitalopram oxalate.
  Each film-coated tablet contains 20 mg escitalopram corresponding to 25.560 mg escitalopram oxalate.
- The other ingredients are lactose monohydrate, crospovidone, povidone K30, microcrystalline cellulose, pregelatinised maize starch and magnesium stearate (E470b) in the tablet core and hypromellose 6cP (E464), titanium dioxide (E171), lactose monohydrate, macrogol 3000, triacetin and black ink (shellac (E904), black iron oxide (E172), propylene glycol (E1520)) in the film-coating
  See section 2 “Escitalopram Krka contains lactose”.

What Escitalopram Krka looks like and contents of the pack
5 mg film-coated tablets: white, round, biconvex film-coated tablets with bevelled edges and diameter 5.5 mm, imprinted with “5” in black colour on one side of the tablet.

10 mg film-coated tablets: white, oval, biconvex film-coated tablets, scored on one side with dimensions 9 x 6 mm, imprinted with “10” in black colour on each side of the tablet. The tablet can be divided into equal doses.

15 mg film-coated tablets: white, round, biconvex film-coated tablets with bevelled edges and diameter 8.5 mm, imprinted with “15” in black colour on one side of the tablet.

20 mg film-coated tablets: white, oval, biconvex film-coated tablets, scored on one side with dimensions 12 x 7.5 mm, imprinted with “20” in black colour on each side of the tablet. The tablet can be divided into equal doses.

Escitalopram Krka film-coated tablets are available in cartons of 14, 20, 28, 30, 50, 56, 60, 90 and 100 tablets in blisters (OPA/Alu/PVC–Alu).
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicine
Denmark, Finland, France, Ireland, Italy, Malta, Spain, Sweden	Escitalopram Krka
Germany	Escitalex
Romania	Elicea
United Kingdom (Northern Ireland)	Escitalopram

This leaflet was last revised in