Package leaflet: Information for the patient

Escitalopram Polpharma 5 mg orodispergeerbare tabletten
Escitalopram Polpharma 10 mg orodispergeerbare tabletten
Escitalopram Polpharma 15 mg orodispergeerbare tabletten
Escitalopram Polpharma 20 mg orodispergeerbare tabletten

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 Polpharma is and what it is used for

Escitalopram Polpharma 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 Polpharma 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).

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

Do not take Escitalopram Polpharma:
- if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section 6).
- if you take other medicines which belongs to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson´s disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section 2 "Other medicines and Escitalopram Polpharma").

Warnings and precautions
Talk to your doctor or pharmacist before taking Escitalopram Polpharma. 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 Polpharma 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 Polpharma 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);
- if you have chronic pain, that is treated with buprenorphine. The use of this medicine together with Escitalopram Polpharma can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Escitalopram Polpharma").

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 Polpharma (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 Polpharma 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 (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Escitalopram Polpharma for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Escitalopram Polpharma 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 Polpharma. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Escitalopram Polpharma in this age group have not yet been demonstrated.

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

Tell your doctor if you are taking any of the following medicines:
- ”Non-selective monoamine oxidase inhibitors (MAOIs)”, containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Escitalopram Polpharma. After stopping Escitalopram Polpharma 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, buprenorphine (opioid medicines to treat acute or chronic pain). Do not use escitalopram together with these medicines without first talking to your doctor. These medicines may interact with Escitalopram Polpharma and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms;
- 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 Polpharma;
- 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 Polpharma 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 cardiovascular diseases), desipramine, clomipramine and nortriptyline (antidepressants) and risperidone, thioridazine and haloperidol (antipsychotics). The dosage of Escitalopram Polpharma 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 Polpharma 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.

Escitalopram Polpharma with food, drink and alcohol
Escitalopram Polpharma should be taken without food (see section 3 "How to take Escitalopram Polpharma").

As with many medicines, combining Escitalopram Polpharma with alcohol is not advisable, although Escitalopram Polpharma 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 Polpharma if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.

Pregnancy
If you take Escitalopram Polpharma 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 Polpharma so they can advise you.

If you take Escitalopram Polpharma 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 Polpharma. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Escitalopram Polpharma 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 used during pregnancy Escitalopram Polpharma should never be stopped abruptly.

Breast-feeding
It is expected that Escitalopram Polpharma will be excreted into breast milk.

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 Polpharma affects you.

Escitalopram Polpharma 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.

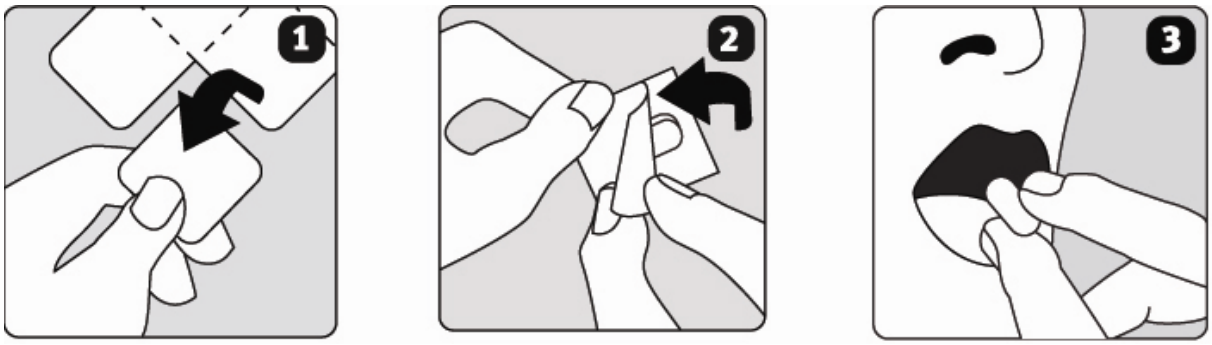
Escitalopram Polpharma contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Escitalopram Polpharma

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

Escitalopram Polpharma orodispersible tablets are taken every day as a single daily dose. You should take Escitalopram Polpharma without food.
Escitalopram Polpharma orodispersible tablets break easily, so you should handle the tablets carefully.

Do not handle the tablets with wet hands as the tablets may break up.
1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing.
3. Place the tablet on your tongue. The tablet will rapidly disintegrate and can be swallowed without water.



<u>Adults</u>
Depression
The normally recommended dose of Escitalopram Polpharma 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 Polpharma 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 Polpharma 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 Polpharma 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 Polpharma 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 Polpharma is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents
Escitalopram Polpharma should not normally be given to children and adolescents. For further information please see section 2 “What you need to know before you take Escitalopram Polpharma”.

Duration of treatment
It may take a couple of weeks before you start to feel better. Continue to take Escitalopram Polpharma 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 Polpharma 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 Polpharma than you should
If you take more than the prescribed dose of Escitalopram Polpharma, 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 Polpharma carton with you when you go to the doctor or hospital.

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

When you stop taking Escitalopram Polpharma, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Escitalopram Polpharma is stopped. The risk is higher, when Escitalopram Polpharma 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 Polpharma, 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, or face, or have difficulties breathing or swallowing (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 heartbeat, 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"
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see "Pregnancy, breast-feeding and fertility" in section 2 for more information.

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
- 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 heartbeat.

Not known *(frequency cannot be estimated from the available data)*:
- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- 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 increased bleeding e.g. from skin and mucous (ecchymosis) and low level of blood platelets (thrombycytopenia)
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in men and 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).

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 Polpharma). 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Escitalopram Polpharma

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 carton and blister foil after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions; store in the original package in order to protect from moisture and light.

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 Polpharma contains

- The active substance is escitalopram.
  Escitalopram Polpharma 5 mg: Each tablet contains 5 mg escitalopram equivalent to 6.3875 mg escitalopram oxalate.
  Escitalopram Polpharma 10 mg: Each tablet contains 10 mg escitalopram equivalent to 12.775 mg escitalopram oxalate.
  Escitalopram Polpharma 15 mg: Each tablet contains 15 mg escitalopram equivalent to 19.1625 mg escitalopram oxalate.
  Escitalopram Polpharma 20 mg: Each tablet contains 20 mg escitalopram equivalent to 25.55 mg escitalopram oxalate.

- The other ingredients are: cellulose, microcrystalline, lactose monohydrate, croscarmellose sodium, polacrilin potassium, acesulfame potassium, neohesperidine-dihydrochalcone, magnesium stearate, peppermint flavor [containing Maltodextrin (maize), Modified starch E1450 (waxy maize) and Peppermint oil (mentha arvensis)], hydrochloric acid, concentrated (for pH adjustment).

What Escitalopram Polpharma looks like and contents of the pack

Escitalopram Polpharma 5 mg: white to off-white round, flat tablets with beveled edges, a diameter of 7 mm and engraved with “5” on one side.
Escitalopram Polpharma 10 mg: white to off-white round, flat tablets with beveled edges, a diameter of 9 mm and engraved with “10” on one side.
Escitalopram Polpharma 15 mg: white to off-white round, flat tablets with beveled edges, a diameter of 11 mm and engraved with “15” on one side.
Escitalopram Polpharma 20 mg: white to off-white round, flat tablets with beveled edges, a diameter of 12 mm and engraved with “20” on one side.

Escitalopram Polpharma orodispersible tablets are available in cartons containing
7, 12, 14, 20, 28, 30, 50, 56, 60, 90, 98, 100, 200 orodispersible tablets in blisters

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Polen

Manufacturer
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Pallini Attiki, 15351
Griekenland

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

Deze bijsluiter is voor het laatst goedgekeurd in november 2023