Package leaflet: Information for the user

Citalopram Vitabalans 20 mg film-coated tablets
citalopram

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 Citalopram Vitabalans is and what it is used for

Citalopram Vitabalans contains the active substance citalopram and belongs to a group of antidepressants (medicines for the treatment of depression) called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain.

Citalopram Vitabalans is used for the treatment of depression, panic disorder (seizures of severe anxiety) with and without agoraphobia, obsessive-compulsive disorder (obsessive thinking and acting) and as preventive treatment against relapse or recurrence of depression.

2. What you need to know before you use Citalopram Vitabalans

Do not use Citalopram Vitabalans

- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6).
- if you are simultaneously taking or if you have taken during the last 14 days so called MAO-inhibitors (e.g. moclobemide (used to treat depression) or selegiline (used to treat Parkinson's disease)). The treatment with MAO-inhibitor should be stopped for at least 14 days before changing to Citalopram Vitabalans. The treatment with Citalopram Vitabalans should be stopped at least seven days before changing to a MAO-inhibitor.
- if you are taking linezolid (antibiotic), unless there are facilities for close observation and monitoring of your blood pressure.
- 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. Also refer to the section *"Other medicines and Citalopram Vitabalans" below*.

Warnings and precautions

Talk to your doctor before using Citalopram Vitabalans.

Please tell your doctor if you have any other condition or illness your doctor should be aware of. In particular, tell your doctor if:

- you have diabetes (see also *"Other medicines and Citalopram Vitabalans"*)
- you are receiving electroconvulsive treatment
- you have a psychotic disease or if you have earlier suffered from mania (feeling of improved or excited mood resulting in unusual behaviour). Citalopram Vitabalans should be discontinued if you enter a manic phase, discuss with your doctor.
- you suffer from impaired liver or kidney function
- you get easily bleedings or bruises (see also *"Other medicines and Citalopram Vitabalans"*), or if you are pregnant (see *"Pregnancy, breast-feeding and fertility"*)
- you have epilepsy. Citalopram Vitabalans should be discontinued, if seizures occur or if there is an increase in the seizure frequence, discuss with your doctor.
- you suffer or have suffered from heart problems or have recently had a heart attack
- 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)
- you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate
- you have eye-problems such as angle-closure glaucoma or history of glaucoma (increased pressure in the eye).

In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during the continued treatment. 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.

Medicines like Citalopram Vitabalans (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.

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.

Children and adolescents
Citalopram Vitabalans should normally not be used for children and adolescent under 18 years. Also, you should know that patients under 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 Citalopram Vitabalans for patients under 18 because he/she decides that this is in their best interests. If you doctor has prescribed Citalopram Vitabalans 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 Citalopram Vitabalans. Also, the long-term safety effects concerning growth, maturation, and cognitive and behavioural development of Citalopram Vitabalans in this age group have not been demonstrated.

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

It is especially important to tell your doctor or pharmacist, if you are taking any of the following medicinal agents:
- MAO-inhibitors (used to treat depression and Parkinson's disease) (please see *"Do not take Citalopram Vitabalans"*)
- linezolid (antibiotic) (please see *"Do not take Citalopram Vitabalans"*)
- pimozide (used to treat mental disorders)
- metoprolol (used to treat high blood pressure)
- 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 citalopram.
- litium and tryptophan (medication used to treat manodepressive diseases)
- imipramine and desipramine (medication used to treat depression)
- sumatriptan or other triptans (migraine medication) medicines that decrease blood levels of potassium or magnesium.
- medicines lowering the seizure threshold, e. g. other antidepressants (tricyclics, SSRI's), antipsychotic medicines (e. g. phenothiazines, thioxanthenes and butyrophenones), mefloquin, bupropion and tramadol (used to treat pain)
- buprenorphine

Treatment with Citalopram Vitabalans may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.

Citalopram Vitabalans may cause bleedings (e.g. skin and mucous bleeding). Simultaneous treatment with medicines, which increase the risk of bleeding, e.g. anticoagulants (medicines used to prevent blood clots, e.g. warfarin), salicylic acid derivatives (e.g. acetyl salisylic acid), NSAIDs (medicines used to treat inflammation and pain), dipyridamol, ticlopidine, atypical antipsychotics (e.g. risperidone), phenothiazines (e.g. chlorpromazine), or tricyclic depressants (e.g. imipramine) may increase this risk.

Citalopram Vitabalans should not be used concomitantly with herbal products containing St John's wort (*Hypericum perforatum*), because the combination may increase the risk of side effects.

DO NOT TAKE Citalopram Vitabalans if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derviatives, 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.

Citalopram Vitabalans with food, drink and alcohol

Citalopram Vitabalans should not be taken together with alcohol, because alcohol may alter the effect of Citalopram Vitabalans. Citalopram Vitabalans tablets can be taken with or without food, but with fluid.

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.

Inform your doctor if you are pregnant or planning to become pregnant.

There is only limited experience concerning the use of Citalopram Vitabalans during pregnancy. Do not use Citalopram Vitabalans during pregnancy, unless specifically directed by your doctor.

The following symptoms have been reported in the newborn immediately or soon after the baby is born, when medicines of the same group as Citalopram Vitabalans have been used during the later stages of pregnancy: trouble with breathing, blueish 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 baby has any of these symptoms when it is born, contact your doctor immediately.

Make sure your midwife and/or doctor know you are on Citalopram Vitabalans. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Vitabalans 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 Citalopram Vitabalans 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 Citalopram Vitabalans so they can advise you.

Citalopram passes over to breast milk. There is a risk of an effect on the baby. Do not use Citalopram Vitabalans during breast-feeding, unless specifically directed by your doctor.

Citalopram has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has been observed as yet.

Driving and using machines

Citalopram Vitabalans may affect your ability to drive a car or use machines. Do not drive or use machines until you know how Citalopram Vitabalans affects you. Read all the information in this leaflet for guidance. Discuss with your doctor, nurse of pharmacist if you are unsure about anything.

3. How to use Citalopram Vitabalans

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

Citalopram Vitabalans is taken once daily, either in the morning or in the evening. Citalopram Vitabalans can be taken with or without food, but with fluid. The tablet can be divided into equal doses.

Tell your doctor or pharmacist if you feel that the effect of Citalopram Vitabalans is too strong or too weak.

Adults
Depression
The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day. Following treatment initiation, an antidepressant effect should not be expected for at least two weeks. Treatment should continue until the patient has been free of symptoms for 4-6 months.

Panic disorder
The starting dose is 10 mg per day for the first week before increasing the dose to 20-30 mg per day. The first therapeutic effect usually appear after 2-4 weeks. The dose may be increased by your doctor to a maximum of 40 mg per day.

Full therapeutic response may take up to 3 months to develop. It may be necessary to continue the treatment for several months.

Obsessive-compulsive disorder
The starting dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg/day Therapeutic effect appear after 2-4 weeks and additional improvement appear during continued treatment.

Preventive treatment
The treatment period is individual, usually yearlong. Discontinuations should happen under close surveillance to avoid relapse.

Reduced renal function
In patients with mild to moderate kidney problems no dosage adjustment is required. However, Citalopram Vitabalans should be used with caution in patients with severe kidney problems.

Reduced hepatic function
The treatment of patients with severe hepatic impairment should be started with half of the normal dose.
Patients with liver complaints should not receive more than 20 mg per day.

Elderly patients (above 65 years of age)
The starting dose should be decreased to half of the recommended dose, e.g. 10-20 mg per day. Elderly patients should not usually receive more than 20 mg per day.

Children and adolescents

Citalopram Vitabalans should normally not be used for children and adolescent under 18 years. For more information please see section 2.

If you take more Citalopram Vitabalans than you should

If you have taken more than the prescribed dose, contact your nearest casualty department or you're your doctor.
Symptoms of overdose include seizures, rapid heartbeat, drowsiness, changes in the electrical activity of the heart, unconsciousness, vomiting, tremor, changes in blood pressure, irregular heartbeat, changes in heart rhythm, feeling sick (nausea), serotonin syndrome, agitation, dizziness, enlarged eye pupils (mydriasis), sweating, bluish skin, breathing too quickly.

If you forget to take Citalopram Vitabalans

Take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Citalopram Vitabalans

Do not stop taking Citalopram Vitabalans until your doctor tells you to. Usually your doctor will help you to reduce your dose slowly over a number of weeks.

When treatment with Citalopram Vitabalans is stopped, especially if it is done abrupt, you may feel discontinuation symptoms. The risk is higher, when Citalopram Vitabalans has been used for a long time or in high doses or when the dose is reduced too quickly.

Discontinuation symptoms include: feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), vomiting, feeling restless or agitated, tremor (shakiness), feeling confused or

disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

Most people find that the symptoms are mild and go away on their own within two weeks. If you get severe withdrawal effects when you stop taking Citalopram Vitabalans, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.
Please see your doctor if you are worried about withdrawal effects when stopping Citalopram Vitabalans.

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. Common side-effects such as nausea, sleepiness, dry mouth and sweating are mostly mild and disappear in most cases during the first weeks of the treatment.

See your doctor or go to the nearest hospital straight away if you get any of the following side effects during treatment:
- swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction) *(rare side effect that may affect up to 1 in 1 000 people)*.
- high fever, trembling, muscle twitches of muscles and anxiety. These may be signs of a rare condition called serotonergic syndrome *(frequency not known, 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 *(frequency not known, cannot be estimated from the available data)*.
- tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium *(rare side effect that may affect up to 1 in 1 000 people)*.

Treatment with Citalopram Vitabalans should be discontinued immediately.

Other side effects that may occur:

Very common *(may affect more than 1 in 10 people)*
- sleepiness, difficulty in sleeping, headache
- dry mouth, feeling sick (nausea)
- increased sweating

Common *(may affect up to 1 in 10 people)*
- lack of appetite, loss of weight
- agitation, decreased sex drive, anxiety, nervousness, confusion, for females: failing to reach an orgasm, abnormal dreams
- tremor, prickling of the skin, dizziness, disturbance in attention
- ringing in the ears (tinnitus)
- yawning
- diarrhea, vomiting, constipation
- itching
- pain in muscles and joints
- for men: problems with ejaculation and erection
- tiredness

Uncommon *(may affect up to 1 in 100 people)*
- increased appetite, weight increased
- aggression, sense of loss of identity, hallucination, mania
- fainting
- large pupils (the dark centre of the eye)

- fast heart beat, slow heart beat
- nettle rash, loss of hair, rash, appearance of red or purple discolorations on the skin (purpura), sensitivity to sunlight
- difficulties urinating
- vaginal bleeding
- swelling of the arms or legs

Rare *(may affect up to 1 in 1 000 people)*
- convulsion grand mal, involuntary movements, taste disturbances
- bleeding
- hepatitis
- pyrexia

Frequency not known *(cannot be estimated from the available data)*
- an increase in bleeding or bruising caused by a decrease in blood platelets
- rash (hypersensitivity)
- inappropriate antidiuretic hormone (ADH) secretion
- decreased level of potassium in blood (including swelling of the skin and mucosa)
- panic attack, grinding teeth, restlessness
- thoughts of harming yourself or thoughts of killing yourself (see *"What you need to know before you use Citalopram Vitabalans"*)
- convulsions, specific movement disorders due to disturbances in certain nerve paths, involuntary movements of the muscles (akathisia), movement disorder
- visual disturbance
- change in the heart's electrical cycle (QT-prolongation, ventricular arrhythmia)
- low blood pressure (e.g. upon standing up)
- nosebleed
- gastrointestinal bleeding (including rectal bleeding)
- abnormal liver function tests
- bleeding disorders including skin and mucosal bleeding (ecchymosis), swelling of the skin and mucosa
- female metrorrhagia (bleeding between periods), painful/persisting erections in men, flow of breast milk in men
- increased blood levels of the hormone prolactin
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding and fertility in section 2 for more information

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

Discontinuation of citalopram (particularly when abrupt) commonly leads to withdrawal symptoms (see *"How to use Citalopram Vitabalans"*).

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 Citalopram Vitabalans

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 after EXP. The expiry date refers to the last day of that month.
Do not use this medicine if you notice damaged tablets or if the tablets have deteriorated.
This medicinal product does not require any special storage conditions.

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 Citalopram Vitabalans contains

Tablet core:
- The active substance is citalopram (as hydrobromide). Each tablet contains 20 mg of citalopram (as hydrobromide).
- The other ingredients are microcrystalline cellulose, mannitol (E421), colloidal anhydrous silica and magnesium stearate.

Tablet coating:
The ingredients are polydextrose, hypromellose, titanium dioxide and macrogol.

What Citalopram Vitabalans looks like and contents of the pack

What Citalopram Vitabalans tablets looks like:
A white, round, convex tablet with a one-side score and logo “2”. Diameter is 8 mm.
The tablet can be divided into equal doses.

Pack sizes:
10, 14, 20, 30, 60 and 100 tablets.

Marketing Authorisation Holder and Manufacturer

Vitabalans Oy
Varastokatu 8
FI-13500 Hämeenlinna
FINLAND

This medicinal product is authorised in the Member States of the EEA under the following names:
Citalopram Vitabalans (CZ, DE, DK, EE, FI, HU, LT, LV, NO, PL, SE, SI, SK)

This leaflet was last revised in 11 April 2024