Package leaflet: Information for the patient

Citalopram ratiopharm 10 mg, filmomhulde tabletten
Citalopram ratiopharm 20 mg, filmomhulde tabletten
Citalopram ratiopharm 40 mg, filmomhulde tabletten

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 ratiopharm* is and what it is used for

Citalopram belongs to a group of antidepressants called selective serotonin re-uptake inhibitors (SSRIs). Everyone has a substance called serotonin in the brain. Low levels of serotonin are thought to be a cause of depression. It is not fully understood how citalopram works, but it may help by increasing the amount of serotonin in the brain.

Citalopram ratiopharm is used to treat
- depression (major depressive episodes)

2. What you need to know before you take *Citalopram ratiopharm*

Do not take *Citalopram ratiopharm*
- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6).
- if you are taking or have recently taken medicines called monoamine oxidase inhibitors (MAOIs; amongst others used to treat depression, e.g. moclobemide). Before starting with *Citalopram ratiopharm*, you must talk to your doctor, because you may have to wait for up to 14 days after quitting the use of a MAOI. The MAOI selegiline (used to treat Parkinson's disease) may be used, but not in doses exceeding 10 mg per day. When changing from *Citalopram ratiopharm* to MAOIs, you have to wait for at least seven days before you start taking MAOIs.
- 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 ratiopharm*" below.
- if you are taking linezolid (used to treat bacterial infections), unless you are closely observed by your doctor and your blood pressure is monitored.

If any of this applies to you please inform your doctor before taking *Citalopram ratiopharm*.

Warnings and precautions

Talk to your doctor before taking *Citalopram ratiopharm*:
- if you are taking any other medicines (see "Other medicines and *Citalopram ratiopharm*").
- 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 diabetes, because your doctor may need to adjust the dosage of insulin or other medicine used to lower your blood sugar.
- if you have epilepsy or a history of fits or start suffering from seizures during treatment with *Citalopram ratiopharm*. Your doctor may decide to discontinue therapy with *Citalopram ratiopharm*, if a seizure occurs.
- if you are having electro-convulsive therapy (ECT).
- if you suffer from episodes of mania/hypomania (overactive behaviour or thoughts). Your doctor may decide to discontinue therapy with *Citalopram ratiopharm* if you are entering a manic phase.
- if you have a history of bleeding disorders or bleed easily or if you are pregnant (see "Pregnancy, breast-feeding and fertility") or if you use medicines which possibly increase tendency to bleed (see section "Other medicines and *Citalopram ratiopharm*").
- if you have other psychiatric conditions (psychosis).
- if you suffer from liver or kidney problems. Your doctor may need to reduce the dose of *Citalopram ratiopharm*.
- if you are above 65 years of age.
- if you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Medicines like *Citalopram ratiopharm* (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
If you are depressed 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, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age
Citalopram ratiopharm 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 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 ratiopharm* for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed *Citalopram ratiopharm* 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 ratiopharm*. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of *Citalopram ratiopharm* in this age group have not yet been demonstrated.

Sense of restlessness/psychomotor agitation
Take special care if you develop symptoms such as inner sense of restlessness and psychomotor agitation such as an inability to sit or stand still usually associated with subjective distress (akathisia). This is most

likely to occur within the first few weeks of treatment. Increasing the dose of *Citalopram ratiopharm* may make these feelings worse (see section 4. “Possible side effects”).

Serotonin syndrome
Tell your doctor immediately, if some of the following symptoms are developing during therapy with *Citalopram ratiopharm*, because then you may have something called serotonin syndrome. The symptoms include: high fever, trembling (tremor), sudden movements of the muscles and agitation. If this happens, your doctor will stop treatment with *Citalopram ratiopharm* immediately.

Reduced levels of sodium in the blood
Citalopram ratiopharm can in rare cases, predominantly in elderly female patients, cause reduced levels of sodium in the blood and an inappropriate secretion of a hormone of the brain regulating the water balance of the body (syndrome of inappropriate anti-diuretic hormone secretion [SIADH]). Inform your doctor if you start feeling sick and unwell with weak muscles or confused while being treated with *Citalopram ratiopharm.*

Withdrawal symptoms seen on discontinuation
Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation of *Citalopram ratiopharm* is abrupt. The risk of withdrawal symptoms may be dependent on several factors including the duration and dose of therapy and the rate of dose reduction. Dizziness, sensory disturbances (including paraesthesia and electric shock sensations), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability, and visual disturbances have been reported. Generally these symptoms are mild to moderate; however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more). It is therefore advised that *Citalopram ratiopharm* should be gradually tapered when discontinuing treatment over a period of several weeks or months, according to your needs.
If intolerable symptoms occur following a decrease in the dose upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, your doctor may continue decreasing the dose, but at a more gradual rate.

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

DO NOT TAKE *Citalopram ratiopharm* 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. 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.

If you are taking or have recently taken any of the medicines in the list below, and you have not already discussed these with your doctor, go back to your doctor and ask what to do. The dose may need to be changed or you may need to be given another medicine.
- monoamine oxidase inhibitors and linezolid (see “Do not take *Citalopram ratiopharm*“)
- selegiline (used to treat Parkinson’s disease)
- buspirone (used to treat anxiety disorders)
- medicines called triptans such as sumatriptan or oxitriptan (used to treat migraine)
- tramadol and similar medicines (used to treat severe pain)
- anticoagulants, dipyridamol and ticlopidine (medicines to thin the blood)
- acetylsalicylic acid, non-steroidal anti-inflammatory drugs (NSAID’s) such as ibuprofen (medicines used to treat inflammation and pain)
- neuroleptics (phenothiazines [e.g. thioridazine], thioxanthenes, butyrophenones [e.g. haloperidol]), atypical antipsychotics, e.g. risperidone (medicines used to treat certain psychiatric conditions)

- tricyclic antidepressants (medicines used to treat depression)
- herbal remedies containing St. John's wort (Hypericum perforatum)
- cimetidine, omeprazole, esomeprazole, lansoprazole (medicines used to lower the production of stomach acid)
- fluconazole (used to treat fungal infections)
- lithium (medicine used to treat mania) and tryptophan (serotonin-precursors)
- imipramine, desipramine, clomipramine, nortriptyline (medicines used to treat depression)
- fluvoxamine (medicine used to treat depression and obsessive compulsive disorder)
- mefloquin (medicine used to treat malaria)
- bupropion (medicine used to treat depression and to support to give up smoking)
- flecainide, propafenone (medicines used to treat irregular heartbeat)
- metoprolol (medicine used to treat cardiac failure)
- medicinal products which may cause low blood levels of potassium or magnesium. Please ask you doctor or pharmacist if the medicinal product(s) you are taking/using concomitantly with *Citalopram ratiopharm* belong(s) to this group.

***Citalopram ratiopharm* with food and alcohol**
It is recommended not to drink alcohol during treatment with *Citalopram ratiopharm*.
Citalopram ratiopharm can be taken with or without food.

Pregnancy, breast-feeding and fertility
Ask your doctor or pharmacist for advice before taking any medicine.

Do not take *Citalopram ratiopharm* if you are pregnant or planning to become pregnant, unless your doctor considers it absolutely necessary.
Make sure your midwife and/or doctor know you are on *Citalopram ratiopharm*. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like *Citalopram ratiopharm* 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.
Also, if you take *Citalopram ratiopharm* during the last 3 months of your pregnancy and until the date of birth you should be aware that the following effects may be seen in your newborn: fits, being too hot or cold, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, overactive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your newborn baby gets any of these symptoms please contact your midwife and/or doctor immediately.
If you take *Citalopram ratiopharm* 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 ratiopharm* so they can advise you.

If you are breast-feeding, ask your doctor for advice. You should not breast-feed your baby when taking *Citalopram ratiopharm* because small amounts of the medicine can pass into the breast milk.

Citalopram 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
Citalopram ratiopharm has minor or moderate influence on the ability to drive and use machines. However, medicinal products influencing the central nervous system can reduce the ability to make judgements and to react to emergencies. Do not drive or use machines until you know how *Citalopram ratiopharm* affects you. Please ask your doctor or pharmacist if you are unsure about anything.

3. How to take *Citalopram ratiopharm*

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

40 mg
Citalopram ratiopharm 40 mg is not suitable for all dosages described below. For these dosages, other products containing citalopram are available on the market.

Use in adults
The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

Use in 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.

Use in patients with special risks
Patients with liver complaints should not receive more than 20 mg per day.

Citalopram ratiopharm should be taken as a single oral dose, either in the morning or in the evening. The film-coated tablet(s) can be taken with or without food, but with fluid.

The effect of *Citalopram ratiopharm* is not felt straight away. It will take at least two weeks before you notice any improvement. After you are free of symptoms, Citalopram should be taken for another 4-6 months.

Discontinuation of therapy
Citalopram ratiopharm should be withdrawn slowly in order to reduce the risk of withdrawal reactions. Your doctor will gradually reduce your dose over a period of at least 1-2 weeks (see "Warnings and precautions").

If you take more *Citalopram ratiopharm* than you should
If you think that you or anyone else may have taken too many film-coated tablets contact your doctor or nearest hospital casualty department immediately.
The following symptoms may occur: irregular heart beat, seizures, changes in heart rhythm, feeling sick (nausea), vomiting, sweating, drowsiness, unconsciousness, fast heart beats, tremor, changes in blood pressure, agitation, dizziness, enlarged eye pupils, bluish skin, breathing too quickly.
Also a serotonin syndrome may occur (symptoms see "Warnings and precautions").

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

If you stop taking *Citalopram ratiopharm*
Do not stop taking *Citalopram ratiopharm* until your doctor tells you. *Citalopram ratiopharm* should be withdrawn slowly, it is advised that the dose is gradually reduced over a period of at least 1-2 weeks. It is important that you follow the instructions of your doctor. Discontinuation of treatment with *Citalopram ratiopharm* particularly if abrupt, may result in the appearance of withdrawal symptoms (see "Warnings and precautions"). Talk to your doctor, if such withdrawal symptoms occur after you stopped taking *Citalopram ratiopharm.*

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.

Serious side effects

If you get any of the following symptoms you should stop taking *Citalopram ratiopharm* and see your doctor immediately:
- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as torsade de pointes;
- difficulty in breathing;
- swelling of the face, lips, tongue or throat that causes difficulty in swallowing or breathing;
- severe itching of the skin (with raised lumps).

Serotonin syndrom has been reported in rare cases in patients treated with these types of antidepressants (SSRIs). Tell your doctor if you experience high fever, trembling (tremor), sudden movements of the muscles and agitation, because these symptoms may indicate the development of this condition. Treatment with *Citalopram ratiopharm* should be discontinued immediately.

If you notice any of the following symptoms you should contact your doctor immediately as your dose may need to be reduced or stopped:
- You start having fits for the first time or fits that you have suffered from in the past become more frequent.
- Your behaviour changes because you feel elated or over excited.
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

Side effects observed with *Citalopram ratiopharm* are in general mild and transient. They are most prominent during the first weeks of treatment and usually attenuate as the depressive state improves.

Very common *(may affect more than 1 in 10 people*)
- sleepiness, difficulty in sleeping, headache
- feeling sick (nausea), dry mouth, increased sweating
- feeling weak and tired (asthenia)
- difficulties of the eyes to adjust to various distances

Common *(may affect up to 1 in 10 people)*
- decreased appetite or lack of appetite, loss of weight
- agitation, nervousness, confusion
- anxiety, abnormal dreaming, lack of memory, apathy
- migraine
- tremor, tingling or numbness in the hands or feet, dizziness
- disturbance in attention
- taste abnormalities
- ringing in the ears (tinnitus)
- heart racing (palpitation), high or low blood pressure
- yawning, rhinitis, sinusitis
- diarrhoea, vomiting, constipation, stomach problems (e.g. stomach pain, indigestion, flatulence), increased salivation
- itching
- pain in muscles and joints
- excessive or abnormally large urination, difficulty urinating
- decreased sex drive
- for females: failing to reach an orgasm, menstrual pain/cramps
- for men: problems with ejaculation and erection
- impotence
- feeling tired

Uncommon ***(may affect up to 1 in 100 people)***
- gain in appetite, gain in weight
- aggression, seeing and hearing things which are not there (hallucinations), overactive behaviour or thoughts (mania), feeling detached from yourself (depersonalisation), euphoria
- sudden loss of consciousness (lasting from a few seconds to several minutes [syncope])
- large pupils (the dark centre of the eye)
- fast or slow heart beat
- nettle rash, loss of hair, rash, bruising easily, sensitivity to light
- difficulties urinating
- abnormally heavy and prolonged menstrual period
- swelling of the arms or legs

Rare ***(may affect up to 1 in 1,000 people)***
- a lower than normal level of sodium in the blood, predominantly in elderly female patients
- increased sex drive
- convulsions, involuntary movements
- bleeding
- inflammation of the liver (hepatitis)
- coughing
- fever
- general feeling of being unwell (malaise)

Very rare ***(may affect up to 1 in 10,000 people)***
- irregular heartbeat

Not known ***(frequency cannot be estimated from the available data)***
- an increase in bleeding or bruising caused by a decrease in blood platelets
- low potassium levels in the blood (hypokalaemia)
- panic attack
- grinding teeth
- unusual muscle movements or stiffness
- feeling restless, involuntary movements of the muscles (akathisia) (see „Warnings and precautions“)
- visual disturbance
- changes in the electrocardiogram (ECG)
- drop in blood pressure as a result of standing up from a sitting or lying position (sometimes accompanied by dizziness)
- nosebleed
- bleeding disorders including gastrointestinal, rectal, skin and mucosal bleeding
- abnormal liver function tests
- sudden swelling of the skin and mucosa due to fluid retention
- uterine bleeding at irregular intervals
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy, breast-feeding and fertility” in section 2 for more information
- in men: painful erections
- increased blood levels of the hormone prolactin
- flow of breast milk in men or in women who are not breast-feeding (galactorrhoea)
- suicidal thoughts/behaviour (see “Warnings and precautions“)
- an increased risk of bone fractures has been observed in patients taking this type of medicines

Any side effects that do occur will usually disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side effects while taking *Citalopram ratiopharm*, please tell your doctor.

Withdrawal symptoms seen on discontinuation
See “Warnings and precautions”.

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 ratiopharm*

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 outer carton and <blister or bottle> after EXP. The expiry date refers to the last day of that month.

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 ratiopharm* contains
The active substance is citalopram.
10 mg
Each film-coated tablet contains 10 mg citalopram (as hydrobromide).

20 mg
Each film-coated tablet contains 20 mg citalopram (as hydrobromide).

40 mg
Each film-coated tablet contains 40 mg citalopram (as hydrobromide).

The other ingredients are:
Tablet core: mannitol, microcrystalline cellulose, colloidal silica (anhydrous), magnesium stearate
Tablet coating: hypromellose, macrogol 6000, titanium dioxide (E171).

What *Citalopram ratiopharm* looks like and contents of the pack
10 mg
Round, white film-coated tablets with a diameter of 6 mm.

20 mg
Round, white film-coated tablets with a break-line and diameter of 8 mm.
The tablets can be divided to equal doses.

40 mg
Round, white film-coated tablets with a break-line and diameter of 10 mm.
The tablets can be divided to equal doses.

Packs of 10, 14, 20, 28, 30, 50, 56, 98, 100, 100x1, 250 and 500 film-coated tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Str. 3

89079 Ulm
Duitsland

Fabrikant
Merckle GmbH
Ludwig Merckle Straße 3
89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 25150 - Citalopram ratiopharm 10 mg, filmomhulde tabletten
RVG 25151 - Citalopram ratiopharm 20 mg, filmomhulde tabletten
RVG 25152 - Citalopram ratiopharm 40 mg, filmomhulde tabletten

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

10 mg

Duitsland:	Citalopram-ratiopharm 10 mg Filmtabletten
Finland:	Citalopram-ratiopharm 10 mg tabletti, Kalvopäällysteinen
Nederland:	Citalopram ratiopharm 10 mg, filmomhulde tabletten
Oostenrijk:	Citalopram "ratiopharm" 10 mg-Filmtabletten

20 mg

België:	Citalopram-ratiopharm 20 mg
Duitsland:	Citalopram-ratiopharm 20 mg Filmtabletten
Finland:	Citalopram-ratiopharm 20 mg tabletti, kalvopäällysteinen
Nederland:	Citalopram ratiopharm 20 mg, filmomhulde tabletten
Oostenrijk:	Citalopram "ratiopharm" 20 mg-Filmtabletten

40 mg

Duitsland:	Citalopram-ratiopharm 40 mg Filmtabletten
Finland:	Citalopram-ratiopharm 40 mg tabletti, kalvopäällysteinen
Nederland:	Citalopram ratiopharm 40 mg, filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in december 2024.