

# BIO CITALOPRAM

Patient information leaflet

## SCHEDULING STATUS:

SS

BIO CITALOPRAM 10 film-coated tablets  
BIO CITALOPRAM 20 film-coated tablets  
BIO CITALOPRAM 30 film-coated tablets  
Citalopram Hydrobromide  
Contains sugar (lactose monohydrate)

## Read all of this leaflet carefully before you start taking BIO CITALOPRAM

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIO CITALOPRAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## WHAT IS IN THIS LEAFLET

- What BIO CITALOPRAM is and what it is used for
- What you need to know before you take BIO CITALOPRAM
- How to take BIO CITALOPRAM
- Possible side effects
- How to store BIO CITALOPRAM
- Contents of the pack and other information

## 1. What BIO CITALOPRAM is and what it is used for

BIO CITALOPRAM is a Selective Serotonin Reuptake Inhibitors (SSRIs) and belongs to a group of medicines called antidepressants. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

*BIO CITALOPRAM is used for the treatment of:*

- depression and prevention of relapse
- people suffering from panic attacks
- people suffering from obsessive-compulsive disorder (OCD).

## 2. What you need to know before you take BIO CITALOPRAM

### Do not take BIO CITALOPRAM:

- If you are hypersensitive (allergic) to citalopram or any of the other ingredients of BIO CITALOPRAM (listed in section 6).
- If you are currently using a monoamine oxidase inhibitor (MAOI), for example, moclobemide, linezolid or selegiline. These are medicines used in the treatment of depression. At least 14 days should elapse between discontinuing the MAOI and initiating therapy with BIO CITALOPRAM. MAOIs should not be introduced for 7 days after discontinuation of BIO CITALOPRAM.
- If you are also taking a medicine containing antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants. Talk to your doctor.
- If you are under 18 years of age.
- If you are pregnant, trying for a baby or breastfeeding.
- If you suffer from severe kidney problems.
- If you have a condition where your heart rhythm is affected and/or you are using medicines to regulate your heart rate (QT-interval prolongation medicines known as Class IA and III antidysrhythmics).
- If you are using certain antibiotic medicines to treat an infection (e.g. moxifloxacin, erythromycin, anti-malarial treatment particularly halofantrine).
- If you are using certain antihistamine medicines used to treat allergy (astemizole, mizolastine).
- 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).

## Warnings and precautions

### Special care should be taken with BIO CITALOPRAM:

- If you are under 18 years of age
- If you are an elderly patient
- If you suffer from liver or kidney problems.
- If you suffer from panic disorder
- If you suffer from low blood levels of sodium.
- If you suffer from Mania
- If you have seizures, a history thereof or are being treated with ECT (electroconvulsive therapy).
- Diabetes (you may need an adjustment of your antidiabetic therapy).
- If you suffer from epilepsy or a history of seizures or fits.
- If you suffer from eye problems, such as certain types of glaucoma.
- If you have a bleeding disorder or have ever suffered from bleeding in the stomach or intestine or if you are pregnant.
- Medicines like BIO CITALOPRAM tablets (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.
- If you have ever had an allergic reaction to this or any other medicine.
- 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 are taking any other medicines, including those available to buy without a prescription, herbal and complementary medicines.
- If you are having any kind of surgery, including dental and emergency treatment, tell your doctor, dentist or surgeon you are taking BIO CITALOPRAM.
- If you are in the early phase of treatment. You should be carefully monitored for improvement of your depression because suicide is an inherent risk in depressed patients.

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of BIO CITALOPRAM treatment it may take several weeks before you experience any improvement. In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during 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.

## 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 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.

## Children and adolescents

BIO CITALOPRAM tablets should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 years 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 for patients under 18 years because he/she decides that this is in their best interests. If your doctor has prescribed BIO CITALOPRAM tablets for a patient under 18 years and if 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 years are taking BIO CITALOPRAM tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of BIO CITALOPRAM in this age group have not yet been demonstrated.

## Other medicines and BIO CITALOPRAM

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Monoamine oxidase inhibitors (MAOI), tricyclic anti-depressants, (medicine used for treatment of depression) such as selegiline, moclobemide, linezolid, amitriptyline or other antipsychotic medicine.
- Lithium (Used to prevent and treat mania) and tryptophan (an anti-depressant)
- Tramadol (a pain killer)
- Sumatriptan (used to treat migraine)
- The herbal remedy St John's Wort (Hypericum perforatum). This should not be taken at the same time as Citalopram.
- Medicines known to affect the blood platelets (e.g. anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac used as painkillers and some antipsychotic drugs and tricyclic antidepressants).
- Linezolid (an).
- Imipramine and desipramine (medicine used for the treatment of depression or bed-wetting).
- Other serotonergic medicines or medicines with serotonergic activity.
- Warfarin (medicine used in the treatment of blood clotting).
- Cimetidine (medicine used for heartburn and stomach ulcers).
- CYP2C19 inhibitors (e.g. omeprazole, esomeprazole, fluconazole, fluvoxamine, lansoprazole, tlclopizole)
- Mefloquine (used to treat malaria).
- Bupropion (used to treat depression).
- Neuroleptics (thioxanthenes and butyrophenones) (used in the treatment of schizophrenia).

- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure. The effects of either drug could be increased, decreased or altered.
- 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, fentiazine derivatives, pimozide, haloperidol), tricyclic antidepressants
- certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine
- certain antihistamines (astemizole, mizolastine).

## BIO CITALOPRAM with food or drink

BIO CITALOPRAM may be taken with or without food in the morning or evening. The effects of alcohol might be increased by the concurrent use of BIO CITALOPRAM.

## Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

## Pregnancy

Safety and efficacy in pregnancy and breastfeeding has not been established. Also, if you take Citalopram 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. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Tablets may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (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 Tablets 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.

## Breastfeeding

BIO CITALOPRAM is excreted into the breast milk.

## Fertility

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

BIO CITALOPRAM can cause drowsiness, dizziness and problems with eye-sight. Make sure your reactions are normal before driving, operating machinery or doing any other jobs which could be dangerous if you are not fully alert or able to see properly.

## BIO CITALOPRAM contains lactose

BIO CITALOPRAM contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take BIO CITALOPRAM.

BIO CITALOPRAM contains lactose monohydrate and persons that are lactose intolerant (the inability to digest and metabolise lactose) can experience bloating, flatulence and abdominal pain when taking BIO CITALOPRAM tablets.

## 3. How to take BIO CITALOPRAM

Do not share medicines prescribed for you with any other person.

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

The dose of BIO CITALOPRAM will be different for different patients, and ranges from 10 – 40 mg. Your doctor will decide on the suitable dose and the duration of your treatment based on your specific needs and medical condition.

If you have the impression that the effect of BIO CITALOPRAM is too strong or too weak, talk to your doctor or pharmacist.

### Elderly:

10 to 20 mg a day as a single dose. The recommended maximum daily dose for the elderly is 20 mg.

### Liver failure:

Mild to moderate liver failure: An initial dose of 10 mg a day as a single dose for two weeks is recommended. The doctor may increase the dose to a maximum of 20 mg daily depending on your response to BIO CITALOPRAM.

### Severe liver failure:

Your doctor will be monitoring you closely while you are on BIO CITALOPRAM. The maximum recommended dose is 20 mg daily.

## If you take more BIO CITALOPRAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

## Symptoms of overdosage may include:

- Nausea (feeling sick)
- Vomiting
- Sweating
- Drowsiness
- Seizures
- Unconsciousness
- Fatal heart beats
- Tremor
- Irregular heart beat
- Change in heart rhythm
- Change in blood pressure
- Serotonin syndrome
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly

## If you forget to take BIO CITALOPRAM

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for advice.

## If you stop taking BIO CITALOPRAM

Withdrawal reactions can occur.

Frequent symptoms include dizziness, paraesthesia (abnormal sensations of the skin such as burning or prickling), headache, anxiety, nausea, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). Abrupt discontinuation of treatment with BIO CITALOPRAM should be avoided. The majority of symptoms experienced on withdrawal of BIO CITALOPRAM are non-serious and self-limiting. If therapy with BIO CITALOPRAM is to be discontinued, it is recommended that the dose be decreased gradually in order to prevent the possibility of a withdrawal syndrome.

## 4. Possible Side Effects

BIO CITALOPRAM can have side effects.

Not all side effects reported for BIO CITALOPRAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO CITALOPRAM, please consult your health care provider for advice.

## If any of the following happens, stop taking BIO CITALOPRAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty in breathing.
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which causes difficulty in swallowing or breathing.
- Severe itching of the skin (with raised lumps).
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO CITALOPRAM. You may need urgent medical attention or hospitalisation.

## Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Deficiency of platelets in the blood (Thromocytopenia)
- Low levels of potassium in the bloodstream
- Low levels of sodium in the bloodstream
- Temporary loss of consciousness (syncope)
- Irregular heartbeat
- Rapid, strong or irregular heartbeat (Palpitations)
- Convulsions (grand mal)
- Escape of blood from a ruptured blood vessel (haemorrhage)
- Serotonin syndrome is a potentially life-threatening reaction to an elevation of serotonin in the body. Medicines that act to block the reuptake of serotonin, slow breakdown, or increase release are implicated in the development of symptoms. The syndrome may be caused by the misuse and/or combination of a variety of medications. If you experience high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome.

- You can develop a rare and unpredictable reaction known as neuroleptic malignant syndrome (NMS). The syndrome is characterized by fever, muscular rigidity and altered mental status
  - Hepatitis
  - Suicidal ideation and self-harm have been reported in children.
  - Producing less urine than is normal for you
  - Slowness of your heart beat
  - Mania, if your behaviour changes because you feel elated or over excited.
  - Rash
  - Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium.
  - Low blood pressure
  - Bleeding in the gastrointestinal tract, from the mouth to the rectum
  - Liver function test abnormal
  - More bleeding than normal after birth of baby (postpartum haemorrhage)
- These are all serious side effects. You may need urgent medical attention.

## Tell your doctor if you notice any of the following:

### Frequent side effects:

- Reduce desire to eat
- Loss of weight
- Decreased sex drive
- Anxiety
- Nervousness
- Confusion
- For females, failing to reach an orgasm
- Abnormal dreams
- Reduced emotions, indifference (apathy)
- Sleepiness
- Sleep disturbance
- Tremor
- Drowsiness
- Headache
- Dizziness
- Agitation
- Paraesthesia (abnormal sensations of the skin such as burning or prickling)
- Impaired concentration
- Migraine
- Loss of memory (amnesia)
- Ringing in the ears (tinnitus)
- Yawning
- rhinitis
- Nausea
- Constipation
- Diarrhoea
- Dry mouth
- Vomiting
- Upper abdominal pain or discomfort (Dyspepsia)
- Stomach pain
- Flatulence (wind)
- Salivation
- Asthenia (weakness or loss of energy)
- Sweating
- Itching of the skin
- Pain in muscles and joints
- For men, problems with ejaculation and erection
- Fatigue

### Less frequent side effects:

- Increased appetite
  - Weight increase
  - Aggression
  - Depersonalisation
  - Hallucination
  - Increased sex drive
  - Panic attack
  - Involuntary habitual grinding of the teeth, typical during sleep (bruxism)
  - Restlessness
  - Abnormality or impairment of voluntary movement (dyskinesia)
  - Taste disturbance
  - Mydriasis (a long continued or excessive dilation of the pupil)
  - Coughing
  - Loss of hair (alopecia)
  - A rash of purple spots on the skin caused by internal bleeding from small blood vessels
  - Sensitivity to sunlight
  - Abnormal heavy bleeding at menstruation
  - Oedema
- Frequency unknown side effects**
- Movement disorder, that makes it hard for you to stay still (akathisia)
  - Eye-sight disturbances
  - Bleeding from the nose (epistaxis)
  - A discoloration of the skin resulting from bleeding underneath, typically caused by bruising (ecchymosis)
  - Swelling around the eyes and lips (angioedemas)
  - Abnormal bleeding that occurs between periods or that is not associated with menstruation (metrorrhagia)
  - Persistent and painful erection of the penis (priapism)
  - milky nipple discharge unrelated to the normal milk production of breast-feeding
  - Temperature above the normal range due to increase in the body temperature (pyrexia)
  - Malaise (a vague feeling of bodily discomfort)
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIO CITALOPRAM.

## 5. How to store BIO CITALOPRAM

- Store at or below 25 °C.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the carton and blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What BIO CITALOPRAM contains

The active substance is citalopram hydrobromide. The other ingredients are maize starch, lactose monohydrate, croscarmellose sodium, glycerin, copolyvidone, magnesium stearate, microcrystalline cellulose and opdy white.

### What BIO CITALOPRAM looks like and contents of the pack

BIO CITALOPRAM 10: Round, biconvex, white coloured film-coated tablets, diameter 5,5 mm, with marking 10 on one side.  
BIO CITALOPRAM 20: Oval, biconvex, scored, white coloured film-coated tablets, dimensions 8 x 5,5 mm, with marking 20 on one side.  
BIO CITALOPRAM 30: Oval, biconvex, scored, white coloured film-coated tablets, dimensions 12,25 x 6 mm, with marking 30 on one side.  
BIO CITALOPRAM 10, 20 and 30 tablets are available in transparent PVC/PvDc/Aluminium blister packs of 30 tablets. Each blister strip contains 10 tablets and 3 blister strips are packed in an outer carton.

## Holder of Certificate of Registration

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BIO CITALOPRAM 20: 42/1.2/1010  
BIO CITALOPRAM 30: 42/1.2/1067

# BIO CITALOPRAM

Pasiëntinligtingsblad

## SKEDULERINGSTATUS:

SS

BIO CITALOPRAM 10 filmbedekte tablette  
BIO CITALOPRAM 20 filmbedekte tablette  
BIO CITALOPRAM 30 filmbedekte tablette  
Sitalopramhidrobromied  
Bevat suiker (laktosemonohidraat).

**Lees hierdie hele blad noukeurig deur voordat u begin om BIO CITALOPRAM te drink.**  
• Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.

- As u nog enige vrae het, moet u 'n dokter, apoteker of ander gesondheidsorgverskaffer asseblief vra.
- BIO CITALOPRAM is vir u persoonlik voorgeskryf en moet nie u medisyne vir ander mense gee nie.

**WAT IN HIERDIE BLAD IS**  
1. Wat BIO CITALOPRAM is en waarvoor dit gebruik word  
2. Wat u moet weet voordat u BIO CITALOPRAM drink  
3. Hoe om BIO CITALOPRAM te drink  
4. Moontlike newe-effekte  
5. Hoe om BIO CITALOPRAM te bêre  
6. Inhoud van die pak en ander inligting

### 1. Wat BIO CITALOPRAM is en waarvoor dit gebruik word

BIO CITALOPRAM is 'n selektiewe serotoninereropameremmer (SSRI) en behoort aan 'n groep medisyne wat antidepressante genoem word. Hierdie medisyne help om sekere chemiese wanbalanse in die brein reg te stel wat die simptome van u siekte veroorsaak.

**BIO CITALOPRAM word gebruik vir die behandeling van:**

- depressie en voorkoming van 'n terugval
- mense wat aan paniekaanvalle ly
- mense wat aan obsessieve-kompulsieve versteuring (OKV - "OCD") ly

### 2. Wat u moet weet voordat u BIO CITALOPRAM drink

**Moenie BIO CITALOPRAM drink nie:**

- as u hypersensitief (allergies) vir sitalopram of vir enige van die ander bestanddele (gelys in afdeling 6) van BIO CITALOPRAM is.
- as u tans 'n monoamienoksidasremmer (MAO-R) gebruik, byvoorbeeld moklobemied, linesoled of selegilien. Hierdie medisyne word vir die behandeling van depressie gebruik. Ten minste 14 dae moet verloop tussen staking van die MAO-R en aanvang van behandeling met BIO CITALOPRAM. MAO-R moet nie binne 7 dae na staking van BIO CITALOPRAM gegee word.
- as u ook medisyne gebruik wat antisigotika bevat (bv. fenotiasienderivate, pimosied, haloperidol), trisikliese antidepressante. Praat met u dokter.
- as u jonger as 18 jaar is.
- as u swanger is of probeer om 'n baba te hê of borsvoed.
- as u ergie nierprobleme het.
- as u 'n toestand het waar u hartritmoe beïnvloed word of as u medisyne gebruik om u hartklop te reguleer (medisyne wat die QT-interval verleng, bekend as Klas IA- en III-antidisritmika).
- as u sekere antibiotika gebruik om 'n infeksie te behandel (bv. moksifloskasiën, eritromisien, malarialmiddels, veral halofantolien).
- as u gebore is of met 'n episode van abnormale hartritmoe gehad het (gesien in 'n EKG, 'n toets wat hartfunksie evalueer).

### Waarskuwings en voorsorgmaatreëls

**Wees besonde versigtig met BIO CITALOPRAM:**

- as u jonger as 18 jaar is.
  - as u 'n bejaarde pasiënt is.
  - as u lever- of nierprobleme het.
  - as u aan 'n paniekversteuring ly.
  - as u aan lae natriumvlakte in die bloed ly.
  - as u aan manje ly.
  - as u toevalle kry, 'n geskiedenis daarvan het of met EKT (elektrokonvulsieve terapie) behandel word.
  - diabetes (u moet moontlike en antidiabetiese middels aanpas).
  - as u aan epilepsie ly of 'n geskiedenis van stuutrekings of toevalle het.
  - as u oogprobleme het, soos sekere soorte gloukoom.
  - as u 'n bloedingstoornis het of ooit aan bloeding in die maag of ingewande gely het of as u swanger is.
  - medisyne soos BIO CITALOPRAM-tablette (sogenaamde SSRI's/SNRI's) kan simptome van seksuele disfunksie veroorsaak (kyk afdeling 4). In sommige gevalle het hierdie simptome voortgeduur nadat die behandeling gestaak is.
  - as u ooit 'n ergie allergiese reaksie op enige ander medisyne gehad het.
  - as u hartprobleme het of oorlangs gehad het of langs 'n hartaanval gehad het.
  - as u 'n stadiqe rustende hartklop het en/u weet dat u soutoutputting het as gevolg van langdurige ernstige diarree en braking (opbring) of vanwêe die gebruik van diuretika (waterablette).
  - as u 'n vinnige of onregelmatige hartklop het, floutes, ineenstorting of duiseligheidervaaranneer opgestaan word wat abnormale werking van die hart kan aandui.
  - as u ander medisyne gebruik, waaronder dié wat u sonder voorskryf kan koop, kruimiddels en aanvullende medisyne.
  - as u enige operasie ondergaan, waaronder tandheelkundige en nooddbehandeling, moet u sê u dokter, tandarts of chirurg sê dat u BIO CITALOPRAM drink.
  - as u in die vroeë fase van behandeling is. U moet noukeurig gemonitor word vir die verbetering van u depressie, want selfdood is 'n inherente risiko vir depressieve pasiënte.
- Soos met ander medisyne wat gebruik word om depressie of verwante siektes te behandel, word die verbetering nie onmiddellik bereik nie. Dit kan 'n paar weke na die aanvang van behandeling met BIO CITALOPRAM neem voordat u enige verbetering ondervind. Aan die begin van die behandeling kan sommige pasiënte eerger angstaar, wat tydens voortgesette behandeling sal verdwyn. Daarom is dit baie belangrik dat u die instruksies van u dokter presies volg en nie die behandeling stop of die dosis verander sonder om u dokter te raadpleeg nie.

### Gedagtes van selfdood en verergering van u depressie of angsvversteuring

As u depressief is en/of angsvversteuring het, kan u soms daarvan dink om uself te beseer of dood te maak. Dit kan erger word as u met behandeling met antidepressante begin, aangesien hierdie medisyne tyd neem om te werk, gewoonlik ongeveer twee weke, maar soms langer.

### Dit sal meer waarskynlik wees dat u so sal dink:

- as u al voorheen daarvan gedink het om uself om die lewe te bring of te beseer.
- as u 'n jong volwassene is. Inligting uit kliniese proewe toon 'n groter risiko vir selfdoodgedrag in volwassenes jonger as 25 jaar met psigiatrisee toestande wat met 'n antidepressant behandel is.

### Kinders en adolescentes

BIO CITALOPRAM-tablette moet nie deur kinders of adolescentes jonger as 18 jaar gebruik word nie. U moet ook weet dat pasiënte jonger as 18 jaar 'n hoë risiko vir newe-effekte het, soos selfdoodpogings, selfdoodgedagtes en vyandighede (hoofsaklik aggressie, weerbarstige gedrag en woeide) wanneer hulle hierdie klas medisyne gebruik. Ten spye hiervan kan u dokter sitalopram aan pasiënte onder 18 jaar voorskryf omdat hy/sy besluit dat dit in hul beste belang is. As u dokter BIO CITALOPRAM-tablette voorskryf het vir u pasiënte jonger as 18 jaar, en as u dit wil bespreek, moet u teruggaan na u dokter toe. U moet u dokter in kennis stel indien enige van die boegenoemde simptome ontwikkel of vererger wanneer pasiënte jonger as 18 jaar BIO CITALOPRAM-tablette gebruik. Die effek van BIO CITALOPRAM op veiligheid oor die lang termyn rakende groei, volwasewording en kognitiwe e gedragsontwikkeling van hierdie ouderdomsgroep is ook nog nie bepaal nie.

### Ander medisyne en BIO CITALOPRAM

- Sé altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).
- Monoamienoksida-remmers (MAO-R's), trisikliese antidepressante (medisyne wat gebruik word vir die behandeling van depressie), soos selegilien, moklobemied, linesoled, amitriptilien of ander antipsigotiese medisyne.
  - Litium (gebruik om manje te voorkom en te behandel) en triptofaan ('n antidepressant)
  - Tramadol ('n pynstillier)
  - Sumatriptan (om migraine te behandel)
  - Die Sint Janskruis [kruiemiddel, Hypericum perforatum ("St John's Wort")]. Dit moet nie op dieselfde tyd as sitalopram gedink word nie.
  - Geneesmiddels wat die bloedplaatjies beïnvloed (bv. antistolmiddels wat gebruik word om bloedklontje te behandel of te voorkom; aspirien en nie-steroid anti-inflammatoriese middels (NSAIDs), soos ibuprofeen en dinkolofan wat gebruik word as pynstilliers, en sommige antipsigotiese middels en trisikliese antidepressante).
  - Linesoled ('n antibioticum).
  - Imipramien en desipramien (medisyne vir die behandeling van depressie of bednatmaak).
  - Ander serotoninerge medisyne of medisyne met serotoninerge aktiwiteit.
  - Warfarien (vir die behandeling van bloedklontje).
  - Simetidien (vir soobrand of maagsiere).
  - CYP2C19-remmers (bv. omeprasool, esomeprasool, flukonasool, fluvoxamien, lansoprasool, tiklopidien).
  - Meflokin (vir malaria).
  - Bupropioon (vir depressie).
  - Neuroleptika (tioxatenene en butirofenone) (vir die behandeling van skisofrenie).

- Metoprolol, 'n beta-blokker vir die behandeling van migraine, sommige harttoestande en hoë bloeddruk. Die effek van enige geneesmiddel kan verhoog, verlaag of verander word.
- Medisyne vir hartritmeprobleme of medisyne wat die hartritmie kan beïnvloed, soos: Klas IA- en III-anti-arritmika, antisigotika (bv. fenotiasienderivate, fentiasienderivate, pimosied, haloperidol), trisikliese antidepressante.
- sekere antimikrobiële middels (bv. sparfloksasien, moksifloskasiën, eritromisien IV, pentamidien, anti-malariamiddels, veral halofantolien).
- sekere antihistamiene (astemisool, misolastien).

### Gebruik van BIO CITALOPRAM saam met kos en drank

BIO CITALOPRAM kan met of sonder voedsel in die ooggend of aand gedrink word.  
Die effekte van alkohol kan versterk word deur die gelyktydige gebruik van BIO CITALOPRAM.

### Swangerskap, borsvoeding en vrugbaarheid

As u swanger is of borsvoed, dink dat u daar swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apoteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u hierdie medisyne gebruik.

### Swangerskap

Die veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie. En as sitalopram in die laaste 3 maande van u swangerskap gebruik en tot en met die bevalling, moet u weet dat die volgende effekte in u pasgeborene gesien kan word: stuutrekings, wees te warm of koud, voedingsprobleme, braking, lae bloedsuikervlak, stywe of slap spiere, ooraktiewe refleksie, bewing, senuatigheid, prikkelbaarheid, lusteloosheid, aanhouende gehuul, slaperigheid of slaapprobleme. As u pasgebore baba enige van hierdie simptome het, moet u vroedvrou en/of dokter asseblief onmiddellik kontak.

Wanneer dit tydens swangerskap gedrink word, veral gedurende die laaste 3 maande van swangerskap, kan medisyne soos sitalopram die risiko verhoog vir 'n ernstige toestand in babas, naamlik die aanhoudende pulmonale hypertensie van die pasgeborene (APHP), wat die baba vinniger laat asemhaal en blou laat lyk. Hierdie simptome begin gewoonlik gedurende die eerste 24 uur nadat die baba gebore is. As dit met u baba gebeur, moet u onmiddellik u vroedvrou en/of dokter onmiddellik kontak.

As u sitalopram teen die einde van u swangerskap drink, kan die risiko vir swaar vaginale bloeding kort na die geboorte hoër wees, veral as u 'n geskiedenis van bloedingsversteurings het.

### Borsvoeding

BIO CITALOPRAM word in borsmelk uitgeskei.

### Fertiliteit

In dierestudies is getoon dat sitalopram die kwaliteit van sperms verlaag. Teoreties kan dit vrugbaarheid beïnvloed, maar die impak op die vrugbaarheid van mense is nog nie waargeneem nie.

### Motorbestuur en gebruik van masjinerie

BIO CITALOPRAM kan slaperigheid, duiseligheid en probleme met visie veroorsaak. Maak seker dat u reaksies normaal is voordat u bestuur, masjinerie gebruik of ander werk verrig wat gevarelik kan wees as u nie heeltemal waaksam is nie of nie goed kan sien nie.

### BIO CITALOPRAM bevat laktose

BIO CITALOPRAM bevat laktose. Pasiënte met die seldsame oorerflike toestand van onverdraagbaarheid van laktose of galaktoze moet nie BIO CITALOPRAM drink nie.

BIO CITALOPRAM bevat laktosemonohidraat en persone wat laktose-onverdraagsaam is (die onvermoë om laktose te verter en te metaboliseer) kan geoblaseerdeheid, winderigheid en buikpyn ondervind wanneer hulle BIO CITALOPRAM-tablette drink.

### 3. Hoe om BIO CITALOPRAM te drink

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.

Drink BIO CITALOPRAM altyd presies soos wat u dokter of apoteker vir u gesê het. Raadpleeg u dokter of apoteker as u nie seker is nie.

Die dosis van BIO CITALOPRAM sal verskillend vir verskillende pasiënte wees, en wissel van 10 - 40 mg. U dokter sal op grond van u spesifieke behoeftes en mediese toestand besluit oor die geskikte dosis en duur van u behandeling.

Praat met u dokter of apoteker as u die indruk het dat die effek van BIO CITALOPRAM te sterk of te swak is.

### Bejaardes:

10 tot 20 mg per dag as 'n enkele dosis. Die aanbevolle maksimum daagliks dosis vir bejaardes is 20 mg.

### Lewerversaking:

Ligte tot matige lewerversaking

'n Aanvanklike dosis van 10 mg per dag as 'n enkele dosis vir twee weke word aanbeveel. Die dokter kan die dosis afgangsheid van u reaksies op BIO CITALOPRAM tot 'n maksimum van 20 mg per dag verhoog.

### Ergie lewerversaking:

U dokter sal u noukeurig monitor terwyl u BIO CITALOPRAM drink. Die maksimum aanbevolle dosis is 20 mg per dag.

### As u meer BIO CITALOPRAM gedrink het as wat u moes

Raadpleeg u dokter in geval van oordosising. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

### Simptome van oordosis kan die volgende insluit:

- Naarheid (voel naar)
- Braking
- Sweet
- Lomerigheid
- Stuutrekings (toevalle)
- Bewusteloosheid
- Fatale hartklop
- Bewerasing
- Onreëlmatige hartklop
- Veranderings in hartritme
- Veranderings in bloeddruk
- Serotoninisindroom
- Agitasie
- Duiseligheid
- Vergrote oogpupille
- Bloueringe vel
- Te vinnig asemhaal

### As u vergeet om BIO CITALOPRAM te drink

Moenie 'n dubbele dosis drink om vir die vergeete individuele dosisse op te maak nie. Gaan voort en drink die volgende tablet op die gewone tyd. As u probleme ervaar om te onthou wanneer om jou medisyne te gebruik, vra vir juu apoteker vir raad.

### As u ophou om BIO CITALOPRAM te drink

Onttrekkingsreaksies kan voorkom. Gereelde simptome is onder meer duiseligheid, parestesie (abnormale gevoel op die vel, soos brandgevoel of prikkels), hoofpyn, ans, naarheid, voel na of bring op, sweet, voel rusteloos of opgewonde, bewing, voel verward of gedisorienteer, voel emosioneel of prikkelbaar, diarree (los stoolgoed), visiestoornisse, fladderende of bonsende hartklop (hartkloppings). Skielike staking van die behandeling met BIO CITALOPRAM moet vermy word. Die meeste simptome wat tydens die onttrekking van BIO CITALOPRAM ervaar word, is nie ernstig nie en selfverkeerd. As behandeling met BIO CITALOPRAM gestaak moet word, word aanbeveel dat die dosis geleidelik verminder word ten einde die ontrekkingsindroom te voorkom.

### 4. Moontlike newe-effekte

BIO CITALOPRAM kan newe-effekte hê. Nie al die newe-effekte wat vir BIO CITALOPRAM aangemeld is, is in hierdie blad opgeneem nie. As u algemeen gesondheidstoestand vererger of as u enige newe-effekte ervaar terwyl u BIO CITALOPRAM drink, moet u u dokter, apoteker of ander gesondheidsorgverskaffer om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om BIO CITALOPRAM te drink en onmiddellik vir u dokter se of na die ongevalle-afdeling van u naaste hospitaal gaan:

- Probleme met asemhaling.
- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling veroorsaak.
- Erge jeuk van die vel (met opgehewe knoppe).
- Vinnige onreëlmatige hartklop of floute wat simptome kan wees van 'n lewensbedreigende toestand wat as torsade de pointes bekend staan.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op BIO CITALOPRAM het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

### Sé dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- Tekort aan bloedplaatjies (trombositopenie)
- Lae vlakke kalium in die bloed
- Lae vlakke natrium in die bloed
- Tydelike verlies van bewussyn (sinkope)
- Onreëlmatige polsslag
- Vinnige, sterk, onreëlmatige hartklop (hartkloppings)
- Stuutrekings (grand mal)
- Bloed ontsnap uit 'n gebroke bloedvat (bloeding)
- Serotoninisindroom is 'n moontlike lewensgevaarlike reaksie op 'n hoëvlak serotonin in die liggaam. Medisyne wat die heropname van serotonin rem, die afbreuk daarvan vertraag die vrystelling verhoog, is betrokke by die ontwikkeling van simptome. Die indroom kan veroorsaak word deur die misbruik en/of kombinasie van 'n verskeidenheid medisyne as u hoë koers, agitasie, verwardheid, bewing of skielike samentrekking van spiere ondervind. Dit kan tekens wees van 'n skaars toestand wat die serotoninse droomb genoem word.

• U kan 'n seldsame en onvoorspelbare reaksie ontwikkel, bekend as die neuroleptiese kwaadaardige syndroom (NKS). Die syndroom word gekenmerk deur koers, spierstryheid en veranderde geestesstatus

• Hepatitis

• Selfdoodgedagtes en selfbesering is in kinders aangemeld

• Produuseer minder urin as wat normaal vir u is

• Stadige hartklop

• Manie, as u gedrag verander omdat u opgewonde of opgewek voel

• Velutslag

• Moegheid, verwardheid en spierstrykings. Dit kan tekens van 'n lae vlak natrium in die bloed wees.

• Lae bloeddruk

• Bloeding in die spysverteringskanal, enige plek vanaf die mond tot die rektum

• Abnormale lewerfunksietoets

• Meer bloeding as normal na die geboorte van die baba (postpartum bloeding)