

<b>Applicant:</b> Oethmaan Biosims (Pty) Ltd	<b>SAHPRA approval date:</b> 09 June 2022
<b>Product:</b> CITALOPRAM 20 OETHMAAN	<b>Dosage form and strength:</b> Each capsule contains citalopram hydrobromide equivalent to 20 mg citalopram

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S5

### CITALOPRAM 20 OETHMAAN (Film-coated Tablets)

Citalopram


Contains sugar (23,0 mg lactose monohydrate)

**Read all of this leaflet carefully before you are given CITALOPRAM 20 OETHMAAN.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CITALOPRAM 20 OETHMAAN 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

1. What CITALOPRAM 20 OETHMAAN is and what it is used for
2. What you need to know before you take CITALOPRAM 20 OETHMAAN
3. How to take CITALOPRAM 20 OETHMAAN
4. Possible side effects
5. How to store CITALOPRAM 20 OETHMAAN
6. Contents of the pack and other information

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	09/06/2022

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## 1. What CITALOPRAM 20 OETHMAAN is and what it is used for

CITALOPRAM 20 OETHMAAN contain the active substance citalopram which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants.


CITALOPRAM 20 OETHMAAN is used for:

- Depression and prevention of relapse.
- Panic disorders.
- Obsessive-compulsive disorder (OCD).

## 2. What you need to know before you are given CITALOPRAM 20 OETHMAAN

### Do not take CITALOPRAM 20 OETHMAAN:

- If you are allergic (hypersensitive) to citalopram or any of the ingredients in the formulation (see “What CITALOPRAM 20 OETHMAAN contains”).
- If you are taking any other medication for depression such as monoamine oxidase inhibitor (MAOI). At least 14 days should elapse between stopping the MAOI and starting with CITALOPRAM 20 OETHMAAN.
- If you have severely impaired kidney function.
- If you are taking pimozide (a medicine used in Tourette’s syndrome)
- If you are taking linezolid, an antibiotic.
- If you are born with or have had an episode of abnormal heart rhythm known as QT interval prolongation (seen at ECG; an examination to evaluate how the heart is functioning).
- If you are pregnant or breastfeeding.
- CITALOPRAM 20 OETHMAAN must not be used by children under the age of 18 years.


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## Warnings and precautions

Take special care with CITALOPRAM 20 OETHMAAN:

- If you are an elderly person.
- If you have liver or kidney impairment.
- If you get seizures (epilepsy) or have a history thereof.
- If you are receiving electroconvulsive treatment (ECT)
- If you have mania or a history of mania.
- If you have pre-existing slow heart rate.
- If you are a diabetic (high blood sugar).
- If you have suicidal thoughts. If you are depressed and/or have anxiety disorders you can sometimes experience increased anxiety symptoms or have thoughts of harming or killing yourselves. These may be increased when first starting antidepressants, including CITALOPRAM 20 OETHMAAN, since these medicines all take time to work, usually about two weeks but sometimes longer. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
- If you have a decreased level of sodium in the blood.
- If you start feeling restless and cannot sit or stand still (akathisia), contact your doctor or pharmacist.
- If you experience a combination of the below mentioned symptoms, CITALOPRAM 20 OETHMAAN should be stopped:
  - Agitation, confusion, disorientation, muscle spasms, hyper-reflexia, tremor, rigidity, incoordination, fever, sweating and diarrhoea.
- If you have bleeding disorders or appearance of bruises or unusual bleeding or if you are taking any medicine that thins the blood.

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- There has been a relation between a group of medicine called SSRI and SNRI and heavy bleeding following birth. CITALOPRAM 20 OETHMAAN belongs to the group of medicines called SSRIs. If you have any bleeding disorders or are pregnant, your doctor will have to change your treatment to an alternative group of medicines.
- If you are taking a herbal medicine St. John's Wort for the treatment of depression.
- 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).

### **Other medicines and CITALOPRAM 20 OETHMAAN**

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

- Do not take any other medicines to treat depression (for example monoamine oxidase inhibitors, imipramine, other serotonergic medicines, and moclobemide) without consulting your doctor as they may interact with CITALOPRAM 20 OETHMAAN.
- Do not use alcohol while using CITALOPRAM 20 OETHMAAN.
- Medicines used to treat blood clotting such as warfarin may interact with CITALOPRAM 20 OETHMAAN. Consult your doctor if you are or have to use such medicines.


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- Medicines used to treat heart burn or stomach ulcer such as cimetidine interacts with the breakdown of citalopram, and the dose of CITALOPRAM 20 OETHMAAN should be changed.

Tell your doctor if you are taking the following medicines:

- Sumatriptan (used to treat migraine)
- Tramadol (used for severe pain)
- Lithium or tryptophan (used for treatment of mental illness with depression)
- Desipramine (used to treat depression)
- Metoprolol (beta-blocker used to treat angina (chest pain) and high blood pressure)
- Selegiline (used to treat Parkinson's disease)
- Blood thinning medicines e.g. warfarin, NSAIDs (such as ibuprofen, diclofenac) and aspirin.
- 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) due to a possible risk of a lowered threshold for seizures (fits), and antidepressants
- Medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derivatives, phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, or certain antihistamines (astemizole, mizolastine), because taking one or more of these medicines with CITALOPRAM 20 OETHMAAN may increase the risk of changes in the electrical activity of the heart.
- St. John's Wort (herbal remedy for depression).

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- Tell your doctor that you are taking CITALOPRAM 20 OETHMAAN before undergoing electroconvulsive therapy.

### **CITALOPRAM 20 OETHMAAN with food and drink and alcohol**

The tablets can be taken with or without food. Avoid the use of alcohol.

### **Pregnancy and breastfeeding and fertility**

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


Safety in pregnancy and breastfeeding has not been established.

Pregnant women should not take CITALOPRAM 20 OETHMAAN nor should mothers breastfeed their babies while taking this medicine, unless you and your doctor have discussed the risks and benefits involved.

#### *Pregnancy*

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in newborn children: irritability, tremor, muscle weakness, persistent crying, and difficulty in sucking or in sleeping.

When taken during pregnancy, particularly in the last 3 months of pregnancy, CITALOPRAM 20 OETHMAAN 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

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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.

### *Breastfeeding*

DO NOT use CITALOPRAM 20 OETHMAAN during breastfeeding.

### *Fertility*

Citalopram, as in CITALOPRAM 20 OETHMAAN, 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 20 OETHMAAN may impair your ability to drive and use machinery, do take care if you feel dizzy, tired or drowsy while using CITALOPRAM 20 OETHMAAN.

### **CITALOPRAM 20 OETHMAAN contains lactose:**


If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CITALOPRAM 20 OETHMAAN.

### **3. How to take CITALOPRAM 20 OETHMAAN**

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

Always take CITALOPRAM 20 OETHMAAN exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

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If you have the impression that the effect of CITALOPRAM 20 OETHMAAN is too strong or too weak talk to your doctor or pharmacist.

You and your doctor should talk about the benefits and risks of treatment with CITALOPRAM 20 OETHMAAN.

The recommended dosage of CITALOPRAM 20 OETHMAAN is one tablet once a day either in the morning or the evening with or without food.

The dose of CITALOPRAM 20 OETHMAAN will be different for different patients and may depend on a number of things, including what the medicine is being used for, and whether or not other medicines are also being taken.

If you have any questions about the proper dose of CITALOPRAM 20 OETHMAAN, ask your doctor.

**If you take more CITALOPRAM 20 OETHMAAN than you should**


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

In the event of overdose, your doctor will treat the symptoms of the side effects which may include tiredness, weakness, sedation, dizziness, tremor, nausea, somnolence and increase heart rate.

**If you forget to take CITALOPRAM 20 OETHMAAN**

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next tablet at the usual time. **Do not take a double dose.**

**If you stop taking CITALOPRAM 20 OETHMAAN**

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**Do not stop taking your medication abruptly, as your doctor will prescribe the gradual lowering of the dose.**

Do not stop taking CITALOPRAM 20 OETHMAAN without asking your doctor first, even when you start to feel better. It is important that you keep taking CITALOPRAM 20 OETHMAAN.

Stopping your treatment abruptly with CITALOPRAM 20 OETHMAAN may lead to the following effects (withdrawal symptoms), such as dizziness, feelings like pins and needles, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), vomiting, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

When stopping CITALOPRAM 20 OETHMAAN, your doctor will help you to reduce your dose slowly over several weeks - this should help reduce the chance of withdrawal effects.


#### **4. Possible side effects:**

CITALOPRAM 20 OETHMAAN can have side effects.

Not all side effects reported for CITALOPRAM 20 OETHMAAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this CITALOPRAM 20 OETHMAAN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking CITALOPRAM 20 OETHMAAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing.

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- If you have thoughts of harming or killing yourself at any time.

These are all very serious side effects. If you have them, you may have had a serious reaction to CITALOPRAM 20 OETHMAAN. 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:


- If you feel restless and cannot sit or stand still, you may have akathisia (feeling of “inner restlessness”, a constant urge to be moving).
- A combination of symptoms (known as “serotonin syndrome”) including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness.
- Rapid and irregular heartbeat sensations
- Tiredness, loss of appetite, weight loss, with or without yellowing of the skin or whites of the eyes (symptoms of abnormal liver function or hepatitis).
- Prolonged and painful erection.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information.
- Symptoms of high fever, confusion, rigid muscles, variable blood pressure, sweating and fast heart rate (Symptoms of Neuroleptic Malignant Syndrome).

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**

- Decreased sex drive (men and women)


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- Sleep problems, sleepiness, tremor
- Nausea, diarrhoea, dry mouth
- Excessive sweating
- Sexual problems (including difficulty maintaining an erection for sexual activity)
- Tiredness

#### Frequency not known

- A decrease in blood platelets, which increases risk of bleeding or bruising
- Reduced water excretion due to high levels of a hormone
- Low levels of salt and potassium in the blood
- Decreased or increased appetite, decreased or increased weight
- Agitation, anxiety, nervousness, feeling confused, abnormal orgasms in women, sleep problems including unusual dreams, aggression, feeling detached from yourself, hallucinations, abnormally high mood, panic attacks, teeth grinding, restlessness
- Feeling of “pins and needles”, dizziness, poor concentration, fainting, fits (seizures), muscle twitching, involuntary movements or problems with balance or co-ordination
- Enlarged dilated pupils, vision problems
- Ringing in the ears
- Slow heartbeat, rapid and irregular heartbeat sensations
- Unexplained bleeding, low blood pressure that happens when standing up from sitting or lying down.
- Yawning, stuffy nose, nosebleed
- Indigestion, vomiting, constipation, bleeding from the gut including the back passage
- Itchy skin, hives, hair loss, rash, purplish rash, sensitivity to sunlight, bruising of the skin, rapid swelling of the tissues around the neck, face, mouth and/or throat

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- Muscle pain, joint pain
- Difficulty passing urine, problems urinating
- Sexual dysfunction, ejaculation problems in men, heavy periods, producing breast milk in men and in women that are not nursing, irregular menstrual period
- Feeling weak, headache, feeling unwell, yawning, swollen ankles, feet and legs, high temperature
- Laboratory test may show the following:
  - blood test results for liver function levels differing from normal

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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 CITALOPRAM 20 OETHMAAN.

### 5. How to store CITALOPRAM 20 OETHMAAN

#### STORE ALL MEDICINES OUT OF REACH OF CHILDREN.


Store below 25 °C.

Store in the original package/container.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use the tablets after the expiry date printed on the container.

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Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What CITALOPRAM 20 OETHMAAN contains

The active substance in each tablet is citalopram hydrobromide equivalent to 20 mg citalopram.

The other ingredients are:

Tablet core: Maize starch, povidone k64, lactose monohydrate, glycerol, microcrystalline cellulose, sodium starch glycolate, magnesium stearate.

Coating: Hypromellose, macrogol 6000, titanium dioxide (E171), talc.

### What CITALOPRAM 20 OETHMAAN looks like and contents of the pack


CITALOPRAM 20 OETHMAAN: White, oblong, biconvex film-coated tablets with a one-sided notch and embossment C20.

CITALOPRAM 20 OETHMAAN are packed in:

Clear PVC/aluminium blister strips containing 10 or 14 tablets each. 3 (10) blister strips to be packed into a carton i.e. 30 tablets per carton or 2 (14's) blister strips to be packed into a carton i.e. 28 tablets per carton.

OR

Clear PVDC coated PVC/aluminium blister strips containing 10 or 14 tablets each. 3 (10) blister strips to be packed into a carton i.e. 30 tablets per carton or 2 (14's) blister strips to be packed into a carton i.e. 28 tablets per carton.

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**7. Holder of Certificate of Registration**


Oethmaan Biosims (Pty) Ltd  
207A Sherwood House  
Greenacres Office Park  
c/o Victory and Rustenberg Roads  
Victory Park  
Johannesburg  
2195

**8. This leaflet was last revised in**

09 June 2022

**9. Registration number**

36/1.2/0469

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