

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S5****PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM****CILORAM 20 mg - citalopram hydrobromide (Film-coated Tablet)****Read all of this leaflet carefully before you start taking CILORAM 20 mg.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **CILORAM 20 mg** 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 **CILORAM 20 mg** is and what it is used for
2. What you need to know before you take **CILORAM 20 mg**
3. How to take **CILORAM 20 mg**
4. Possible side effects
5. How to store **CILORAM 20 mg**
6. Contents of the pack and other information

1. What CILORAM 20 mg is and what it is used for

CILORAM 20 mg is a psychoanaleptic medicine used for the following:

Treatment of depression and prevention of relapse.

Treatment of panic disorder with or without agoraphobia.

Treatment of obsessive compulsive disorder (OCD).

2. What you need to know before you take CILORAM 20 mg

Do not take CILORAM 20 mg:

- if you are hypersensitive (allergic) to citalopram hydrobromide or any of the other ingredients of **CILORAM 20 mg** (see section 6).
- if you have severely impaired kidney function (creatinine clearance of less than 20 ml/min).
- if you have an inborn heart condition where you may have irregular heartbeats (QT-prolongation).
- if you are taking medicines that may prolong the QT interval e.g. pimozide.
- if you are taking medicines that fall into the class of monoamine oxidase inhibitors which are commonly used to treat depression.
- if you are pregnant or breastfeeding.
- if you are younger than 18 years.

Warnings and precautions

Take special care with CILORAM 20 mg:

- If you enter the manic phase stop using **CILORAM 20 mg**, as suicide is an inherent risk in depressed patients.
- If you suffer from epilepsy or a history of such disorders (avoid the use of **CILORAM 20 mg** if the epilepsy is poorly controlled).
- If you suffer from congestive heart failure, slow heartbeats or if you are taking any other medication that affects your heartbeat, you need to be monitored closely by your doctor and undergo regular ECG monitoring.
- If you suffer from a disease or condition which causes lower than normal potassium or magnesium levels in your blood.
- If you suffer from liver problems, as your dose needs to be lowered accordingly.
- If you have a slow heart rate.
- If you suffer from diabetes mellitus, as it may cause a rare occurrence of hypoglycaemia where your blood sugar drops too low.
- If your dose of **CILORAM 20 mg** is increased, you may experience symptoms of serotonin syndrome. For possible symptoms refer to section 4.
- If you are pregnant (see 'Pregnancy').

Other medicines and COXETORI

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Inform your doctor if you are taking any of the following medicines:

- **CILORAM 20 mg** should not be taken with medicines known as monoamine oxidase inhibitors (MAOI), which are commonly used to treat depression, as it may cause serious or life-threatening reactions.
- If you take **CILORAM 20 mg** with imipramine, a medicine used for depression, it may cause an increase in the effect of imipramine.
- If you take other serotonergic medicines or medicines with serotonergic activity for example linezolid (an antibiotic), St. John's Wort (a herbal remedy used to treat depression), moclobemide (a MAOI used for depression) with **CILORAM 20 mg**, it may increase your risk of developing serotonin syndrome which may be fatal.
- The effects of alcohol may be increased if taken with **CILORAM 20 mg**.
- The anticoagulant activity of warfarin may be increased if taken with **CILORAM 20 mg**, which will result in problems with blood clotting.
- The stomach acid-reducing effect of cimetidine is increased when taken with **CILORAM 20 mg**.
- Taking **CILORAM 20 mg** with medicines that prolong your QT interval of your heartbeat for example pimozide, used as an antipsychotic medicine, will further prolong your QT interval.

Pregnancy and breastfeeding:

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **CILORAM 20 mg**.

Newborn babies should be observed if the use of **CILORAM 20 mg** continues into the later stages of pregnancy, in particular the third trimester. Sudden discontinuation of the use of **CILORAM 20 mg** should be avoided during pregnancy. Consult your doctor before you stop taking **CILORAM 20 mg**.

If you take **CILORAM 20 mg** 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 **CILORAM 20 mg** so they can advise you.

Please let your doctor or other healthcare professional know if you notice the following symptoms in your newborn baby:

- Respiratory distress (grunting noises, rapid and shallow breathing);
- Cyanosis (bluish discoloration of the lips, fingers and mucous membranes);
- Apnoea (shallow breathing or pauses during breathing);
- Seizures;
- Temperature instability;
- Feeding difficulty;
- Vomiting;
- Hypoglycaemia (sweating, jitteriness);
- Hypertonia & hyperreflexia (stiffness in muscles, inability to relax muscles);
- Hypotonia (decrease in muscle tone);
- Tremor (muscle twitching);
- Irritability;
- Lethargy and somnolence (being very sleepy and unresponsive);
- Constant crying;
- Difficulty sleeping.

These symptoms could be caused by the effect of taking **CILORAM 20 mg** or the effect of discontinuing treatment with **CILORAM 20 mg**. In a majority of these cases, the complications begin immediately or soon after delivery.

Driving and using machines:

The potential for dizziness, impaired concentration, confusion and headache should be taken into account before patients on **CILORAM 20 mg** drive or use machinery.

CILORAM 20 mg contains lactose.

CILORAM 20 mg contains lactose and should not be taken if you are lactose intolerant or suffer from a condition called Lapp lactase deficiency or glucose-galactose malabsorption.

3. How to take CILORAM 20 mg

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

Always take **CILORAM 20 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with **CILORAM 20 mg** will last. Do not stop treatment early, because your doctor needs to slowly decrease the dosage taken daily. If you have the impression that the effect of **CILORAM 20 mg** is too strong or too weak, tell your doctor or pharmacist.

Adults:

Treating depression

The usual starting dose is 20 mg daily. Dependent on individual patient response this may be increased to a maximum of 40 mg daily.

Swallow the tablet, do not chew. The daily single dose may be taken in the morning or evening, not necessarily with food.

Duration of treatment

The antidepressant effect usually sets in after two to four weeks. Treatment with antidepressants is symptomatic and must therefore be continued for an appropriate length of time, usually up to six months after recovery in order to prevent relapse.

Treating Panic Disorder

A single dose of 10 mg is recommended for the first week before increasing the dose to 20 mg daily. The dose may be further increased, up to a maximum of 40 mg daily, dependent on individual patient response.

Treating OCD

An initial dose of 20 mg is recommended. Although the dose effect has not been demonstrated, this dose can be increased in increments of 20 mg to 40 mg daily, if necessary, based on clinical judgement.

Duration of Treatment

The onset of action in treating OCD is two to four weeks with further improvement over time.

Elderly:

The recommended daily dose is 10 mg - 20 mg. Dependent on individual patient response this may be increased to a maximum of 20 mg daily.

Children up to 18 years of age:

Not recommended, as safety and efficacy have not been established.

Reduced hepatic function:

Dosage should be halved.

Reduced renal function:

Dosage adjustment is not necessary in cases of mild or moderate renal impairment.

Duration of treatment:

A treatment period of at least six months is usually necessary to minimise potential for relapse. When stopping therapy,

CILORAM 20 mg should be gradually withdrawn over a couple of weeks.

If you take more CILORAM 20 mg than you should:

Overdosage may result in tiredness, weakness, sedation, dizziness, tremor, nausea and somnolence.

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

If you forget to take CILORAM 20 mg:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking CILORAM 20 mg:

Treatment with **CILORAM 20 mg** should not be stopped abruptly. Your doctor will gradually decrease your dose over a period of time.

If you suddenly stop taking **CILORAM 20 mg** you may experience the following withdrawal effects:

- Irritability;
- Anxiety;
- Insomnia or vivid dreams;
- Headaches;
- Dizziness;
- Tiredness;
- Flu-like symptoms, including muscle aches and chills;
- Nausea.

4. Possible side effects

CILORAM 20 mg can have side effects.

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

If you experience any of the following side effects, please contact your doctor or go to your nearest hospital immediately:

- A sudden allergic reaction which may cause an itchy rash and/or swelling of the face or throat which causes difficulty breathing.
- Chest pain, fast or slow heartbeat, shortness of breath, dizziness or fainting as it may indicate that you have a change in the electrical activity of your heart caused by QT prolongation or torsades de pointes.
- Serotonin syndrome which may manifest with the following symptoms: agitation, hallucinations, coma or other changes in mental status, co-ordination problems, muscle twitching, sweating, vomiting or diarrhoea.

If you experience the following side effects, you should contact your doctor as soon as possible:

- Sleep disturbances and difficulty sleeping;
- “Pins and needles” feeling through your body;
- Fatigue;
- Restlessness;
- Headache;
- Confusion;
- Impaired concentration;
- Convulsions/fits;
- Changes in your weight;
- Dry mouth;
- Constipation or diarrhoea;
- Digestion problems such as: a bloated feeling, heart burn, pain in the upper abdomen;
- Problems during urination;
- Sexual dysfunction such as decreased libido, problems with ejaculation, inability to orgasm;
- Eye disturbances;
- Nasal congestion;
- Yawning;
- Suicidal thoughts;
- Low muscle strength;
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see ‘Pregnancy’ in section 2 for more information.

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 **CILORAM 20 mg**.

5. How to store CILORAM 20 mg

Store all medicine out of reach of children.

Do not store above 25 °C. Store in a cool, dry place.

Return all unused medicine to your pharmacist.

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

6. Content of the pack and other information

What CILORAM 20 mg contains

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

The other ingredients are copovidone, cellulose microcrystalline, croscarmellose sodium, lactose monohydrate, magnesium stearate and maize starch. **CILORAM 20 mg** is coated with Opadry white which consists of hypromellose, macrogol and titanium dioxide.

Contains sugar (lactose monohydrate 45,72 mg).

What CILORAM 20 mg looks like and contents of the pack

White coloured, biconvex, capsule-shaped film coated tablets debossed with 'A' on one side and with a score-line in between '0' and '6' on the other side.

1. Blister pack

Tablets are packed in Clear PVC (250 microns) coated with PVdC (60 gsm) as the forming material and aluminium foil (25 microns) as the lidding material.

Pack size: 28's: Each carton contains 2 blisters of 14 tablets each.

30's: Each carton contains 3 blisters of 10 tablets each.

2. HDPE container

Tablets are packed in a HDPE container with a stock ribbed closure and induction sealing wad. The void space in the container is filled with a rayon coil.

Pack size: 28's, 30's

Holder of Certificate of Registration

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