

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S5****CILORAM 20 mg, film-coated tablet**

Citalopram hydrobromide

Contains sugar (lactose monohydrate)

CILORAM 20 mg contains 45,72 mg lactose monohydrate per film-coated tablet.

Read all of this leaflet carefully before you start taking CILORAM.

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

1. What CILORAM is and what it is used for

CILORAM belongs to a group of antidepressants called Selective Serotonin Reuptake Inhibitors (SSRI's). These medicine act on the serotonin system in the brain by increasing the serotonin level which plays a role in treating depression and related substances.

CILORAM is used for:

Treatment of depression and when you feel better, to prevent these symptoms from recurring.

Treatment of panic disorder with or without an anxiety disorder in which you fear and avoid places or situations where you might feel panicked, trapped, helpless or embarrassed.

Treatment of obsessive compulsive disorder (OCD).

2. What you need to know before you take CILORAM

Do not take CILORAM:

- if you are hypersensitive (allergic) to citalopram hydrobromide or any of the other ingredients of CILORAM (see section 6).
- if you have severely impaired kidney function (creatinine clearance of less than 30 ml/min).
- if you have an inborn heart condition where you may have irregular heartbeats (QT-prolongation).
- if you are taking a medicine called 'pimozide' (see '**Other medicines and CILORAM**').
- if you are taking medicines that fall into the class of monoamine oxidase inhibitors (MAOIs). MAOI include medicine such selegiline (used in the treatment of Parkinson's disease) and moclobemide (used for treating depression). At least 14 days should pass between stopping the MAOI medicine and starting with CILORAM. MAOIs should not be taken for 7 days after you stop taking CILORAM.
- if you are pregnant or breastfeeding.
- if you are younger than 18 years.
- if you are taking a certain type of antibiotic called linezolid (see '**Other medicines and CILORAM**').

Warnings and precautions

Take special care with CILORAM:

A lower dose is recommended in elderly patients.

If you suffer from liver or kidney problems, as your dose needs to be lowered accordingly.

If you are pregnant (see '**Pregnancy, breastfeeding and fertility**')

Seizures

If you suffer from epilepsy (avoid the use of CILORAM if the epilepsy is poorly controlled). Treatment should be stopped if seizures (fits) occur or if there is an increase in the number of seizures.

ECT (electroconvulsive therapy)

There is limited data available for the use of CILORAM and receiving electroconvulsive treatment (ECT) simultaneously.

Mania or history of mania

If you have episodes of mania stop using CILORAM, as suicide is an inherent risk in depressed patients.

Diabetes mellitus

If you suffer from diabetes mellitus, as it may cause a rare occurrence of hypoglycaemia where your blood sugar drops too low. The dosage of insulin and/or oral anti-diabetic medication may need to be adjusted.

CILORAM should not be used with medicine to treat depression such as imipramine or moclobemide; alcohol; a medicine called 'warfarin' (to treat/prevent blood clots) and cimetidine (medicine to treat stomach ulcers) (see '**Other medicines and CILORAM**')

Serotonin syndrome

You may experience symptoms of serotonin syndrome. A combination of symptoms such as agitation, muscle twitching and high fever may indicate that you are developing this syndrome. Treatment with CILORAM should be stopped immediately.

Serotonergic medicines

CILORAM should not be used with medicines that modifies the effects of serotonin in your body, such as medicine to treat migraines (sumatriptan); a certain type of pain medicine (tramadol) or amino-acid supplements (oxitriptan and tryptophan).

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 CILORAM, since it takes time to work.

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 young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

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

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Paradoxical anxiety

If you suffer from panic disorder, you may experience increased anxiety symptoms at the start of the treatment with CILORAM. These symptoms will usually go away within the first two weeks of starting treatment. It may also be helpful to start with a low dose.

Hyponatraemia (low sodium)

Low sodium blood levels may develop if you are using CILORAM. Sodium levels will return to normal when CILORAM is stopped. Female patients are at a higher risk for developing low sodium.

Akathisia/psychomotor restlessness (movement disorder)

The use of CILORAM may lead to the development of a feeling of muscle quivering, restlessness and inability to sit still. The dose of CILORAM may not be increased if you develop any of these symptoms.

Use in children and adolescents under 18 years of age

CILORAM should not be used for children and adolescents under 18 years. Patients under 18 have an increased risk of side-effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines. There are also no long-term safety data available to know what the effect CILORAM therapy will be on the growth and mental developing of children and adolescents.

QT-Prolongation and torsades de pointes

CILORAM causes dose-dependent QT prolongation (extended interval between the heart contracting and relaxing) and should not be used if you suffer from a heartbeat condition called 'long QT syndrome'.

CILORAM may also cause abnormal heart rhythm (torsades de pointes), mostly occurring in female patients with low potassium levels or a pre-existing QT-prolongation or other heart diseases.

Caution if advised if you have a slow heart rate or if you recently had a heart attack or heart failure.

If you suffer from a disease or condition which causes lower than normal potassium or magnesium levels in your blood it increases the risk of developing irregular heartbeats. Your potassium and magnesium levels must first be corrected before you start taking CILORAM.

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.

Haemorrhage (bleeding inside the body)

CILORAM may increase the risk of heavy vaginal bleeding shortly after birth (postpartum haemorrhage).

There have been reports of bleeding tendencies. You should be careful if you use CILORAM together with other medication that affects bleeding or if you have a history of bleeding disorders.

Withdrawal symptoms

If you use CILORAM for a long period, sudden discontinuation of CILORAM may result in withdrawal symptoms such as dizziness, sensory disturbances, sleep disturbances, agitation, anxiety nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability and visual disturbances. Treatment should be gradually tapered off over a period of several weeks or months to avoid withdrawal symptoms.

Angle-Closure Glaucoma

CILORAM may cause extended dilation of the pupil which may lead to blocked drainage canals in the eye, resulting in sudden rise in intra-eye pressure ('narrow-angle glaucoma'). Take special care if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

St. John's Wort

Taking St. John's Wort (a plant used for mental health conditions) together with CILORAM may result in undesirable effects.

Sexual dysfunction

Taking CILORAM may cause symptoms of sexual dysfunction.

Special information relating to your disease

Improvement is not achieved immediately. After the start of CILORAM treatment it may take several weeks before you experience any improvement.

In the treatment of panic disorder it usually takes 3 months before any improvement is seen. In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during the continued treatment.

Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor.

Occasionally, the symptoms of depression or panic disorder may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult, i.e., under 25 years of age and you have not used antidepressant medicines before.

Some patients with manic-depressive illness may enter a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness, and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Sometimes you may be unaware of the above-mentioned symptoms and therefore you may find it helpful to ask a friend or relative to help you to observe the possible signs of change in your behaviour.

Tell your doctor immediately or contact the nearest hospital if you have distressing thoughts or experiences or if any of the above-mentioned symptoms occurs during the treatment.

Other medicines and CILORAM

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

(This includes complementary or traditional medicines.)

Do not take CILORAM

- If you take 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 pimozide used as an antipsychotic medicine, it will further prolong your QT interval.
- 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-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine).

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

- Medicines containing selegiline (used to treat Parkinson's disease).
- Imipramine, a medicine used for depression, it may cause an increase in the effect of imipramine.
- Lithium (used to prevent and treat mania) and tryptophan (used to treat depression)
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain) may increase the risk of side effects; if you get unusual symptoms when using this combination, you should see your doctor.
- 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, it may increase your risk of developing serotonin syndrome which may be fatal.
- The effects of alcohol may be increased if taken with CILORAM.
- Warfarin - the anticoagulant activity of warfarin may be increased if taken with CILORAM, which will result in problems with blood clotting.
- Medicines known to affect the blood platelets (e.g. aspirin and non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen and diclofenac used as painkillers.
- Mefloquine (used to treat malaria).
- Bupropion (used to treat depression).
- The stomach acid-reducing effect of cimetidine is increased when taken with CILORAM.
- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure.

Pregnancy, breastfeeding and fertility

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.

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

If you take CILORAM 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 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 or the effect of discontinuing treatment with CILORAM. 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 drive or use machinery.

CILORAM contains lactose.

CILORAM 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

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

Always take CILORAM 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 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 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.

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.

Poor metabolisers of CYP2C19

An initial dose of 10 mg daily for the first two weeks of treatment, then the dose may be increased to a maximum of 20 mg daily.

How and when to take CILORAM

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:

A treatment period of at least six months is usually necessary to minimise potential for relapse. When stopping therapy, CILORAM should be gradually withdrawn over a couple of weeks.

If you take more CILORAM 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:

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

If you stop taking CILORAM:

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

If you suddenly stop taking CILORAM 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 can have side effects.

Not all side effects reported for CILORAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CILORAM, 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: high fever agitation, hallucinations, coma or other changes in mental status, co-ordination problems, muscle twitching, sweating, vomiting or diarrhoea.
- Neuroleptic malignant syndrome – a life-threatening reaction characterized by fever, altered mental status, muscle rigidity and autonomic dysfunction.
- Unusual bleeds, including gastrointestinal bleeds

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:

- Sexual dysfunction such as decreased libido, problems with ejaculation, inability to orgasm
- Sleep disturbances including abnormal dreams and difficulty sleeping
- Agitation, anxiety, nervousness, and confusion
- Headache and migraine
- “Pins and needles” feeling through your body

- Shaking ('tremors')
- Dizziness
- Impaired concentration
- Forgetfulness
- Lack of enthusiasm
- Extreme tiredness, lack of energy (fatigue)
- Ringing in the ears
- Palpitations (rapid, strong or irregular heartbeat)
- Runny nose, sneezing, blocked nose (nasal congestion)
- Yawning
- Constipation or diarrhoea
- Nausea or vomiting
- Dry mouth
- Digestion problems such as: a bloated feeling, heart burn, pain in the upper abdomen
- Salivary glands produce more saliva than usual
- Increased sweating or itchy skin
- Muscle pain and joint stiffness
- Decreased appetite and weight loss

Less frequent side effects:

- Feelings of aggression or disconnectedness; experiencing unreasonable happiness ('mania'),
- Seeing or hearing things that don't exist ('hallucinations')
- Increased libido
- Temporary loss of consciousness caused by a fall in blood pressure (syncope)
- Changes in your weight
- Convulsions/fits

- Involuntary movements of the face, arms, legs or trunk ('dyskinesia')
- Taste disturbances
- Extended dilation of the pupil (mydriasis) which may lead to blocked drainage canals in the eye, resulting in sudden rise in intra-eye pressure ('narrow angle glaucoma')
- Slow or fast heartbeat
- Bleeding inside the body (haemorrhage)
- Coughing
- Inflammation of the liver
- Rash; red itchy hives; purple-coloured spots on the skin; extreme sensitivity to the sun; sudden hair loss
- Low muscle strength
- Problems during urination
- Menstrual bleeding lasting for longer than 7 days
- Suicidal thoughts and self-harm have been reported in children
- Swollen ankles, feet and legs due to fluid retention
- General feeling of discomfort, illness, or unease whose exact cause is difficult to identify
- Increased appetite and weight increased
- Low sodium

Frequency unknown:

- Panic attacks; grinding of teeth; restlessness, suicidal thoughts
- Inappropriate anti-diuretic hormone secretion (helps to control blood pressure)
- A movement disorder that makes it hard for you to sit still; involuntary movements
- Eye disturbances
- Low blood pressure when standing up from sitting ('Orthostatic hypotension')
- Nose bleeding
- Abnormal liver function tests

- Discoloration of the skin resulting from bleeding underneath; swelling underneath the skin
- Female: Bleeding from the uterus between menstrual periods
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage). (see '**Pregnancy, breastfeeding and fertility**')
- Male: persistent, painful erection
- One or both breasts unexpectedly produce milk
- Low blood platelet count
- Low potassium level

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.

5. How to store CILORAM

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 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 is coated with Opadry white which consists of hypromellose, macrogol and titanium dioxide.

What CILORAM 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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