

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.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **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.

1. 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.

Contains sugar (lactose monohydrate).

2. WHAT CILORAM IS USED FOR

CILORAM 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).

3. BEFORE YOU TAKE CILORAM

Do not take CILORAM:

- if you are hypersensitive (allergic) to citalopram hydrobromide or any of the other ingredients of **CILORAM**.
- 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.

Take special care with CILORAM:

- If you enter the manic phase stop using **CILORAM**.
- 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** if the epilepsy is poorly controlled).
- If you suffer from congestive heart failure, slow heartbeats or if you are taking any another 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** is increased you may experience symptoms of serotonin syndrome. For possible symptoms refer to "5. POSSIBLE SIDE EFFECTS".

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**.

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

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 machinery:

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

Important information about some of the ingredients of CILORAM:

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.

Effects when treatment with CILORAM is stopped:

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.

Taking other medicines with CILORAM:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **CILORAM** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

- **CILORAM** 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** 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** it may increase your risk of developing serotonin syndrome which may be fatal.

- The effects of alcohol may be increased if taken with **CILORAM**.
- The anticoagulant activity of warfarin may be increased if taken with **CILORAM**, which will result in problems with blood clotting.
- The stomach acid-reducing effect of cimetidine is increased when taken with **CILORAM**.
- Taking **CILORAM** with medicines that prolong your QT interval of your heart beat for example pimozide, used as an antipsychotic medicine, will further prolong your QT interval.

4. 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.

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** should be gradually withdrawn during 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.

5. 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 health care 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 bloated feeling, heart burn, pain in the upper abdomen
- Problems during urination
- Sexual dysfunction such as decreased libido, decreased libido, problems with ejaculation, inability to orgasm
- Eye disturbances
- Nasal congestion
- Yawning
- Suicidal thoughts
- Low muscle strength

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF CILORAM

Keep all medicines out of the reach and sight 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).

7. PRESENTATION OF CILORAM

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 rayon coil.

Pack size: 28's, 30's

8. IDENTIFICATION OF CILORAM 20 mg

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.

9. REGISTRATION NUMBER/REFERENCE NUMBER

CILORAM 20 mg: A40/1.2/0564

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Novagen Pharma (Pty) Ltd.

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11. DATE OF PUBLICATION

Registration date: 13 April 2007.

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