

CELAPRAM®

Citalopram Film Coated Tablets 20mg

What is in this leaflet

Please read this leaflet carefully before you start taking Celapram.

This leaflet answers some common questions about Celapram.

It does not contain all the information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Celapram against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What Celapram is used for

Celapram is used to treat depression and help prevent potential recurrence of the symptoms of depression.

Depression is longer lasting and/or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. This may affect your whole body and may cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

Celapram contains the active ingredient citalopram hydrobromide. It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why Celapram has been prescribed for you.

This medicine is available only with a doctor's prescription.

Celapram is not addictive. However, if you suddenly stop taking it, you may get side effects.

Tell your doctor if you get any side effects after stopping Celapram.

Before you take Celapram

When you must not take it

Do not take Celapram if you have an allergy to:

- any medicine containing citalopram or escitalopram
- any other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Celapram at the same time as the following other medicines:

- pimozone, a medicine used to treat mental health disorders
- monoamine oxidase inhibitors (MAOIs), such as phenelzine, tranylcypromine and moclobemide (a reversible MAOI), which are also used for the treatment of depression, and linezolid (an antibiotic). ONE day must elapse after you have finished taking moclobemide before you start taking Celapram. If you have taken any other MAOI you will need to wait 14 days. After stopping Celapram you must allow 14 days before taking any MAOI including moclobemide.
- Herbal remedies containing St John's Wort (*Hypericum perforatum*)

Taking Celapram with MAOIs may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know when it is safe to start Celapram after the MAOI has been stopped.

Ask your doctor or pharmacist if you are unsure as to whether or not you have been taking one of these medicines.

Do not take this medicine if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine unless you and your doctor have discussed the risks and benefits involved.

The active ingredient in Celapram passes into breast milk and there is

a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Do not take Celapram if you have:

- a heart condition called 'congenital long QT syndrome'. At high doses, Celapram can cause changes in the way that your heart beats. See your doctor immediately if you experience an irregular heartbeat, shortness of breath, dizziness or fainting while taking Celapram
- hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Celapram tablets contain lactose.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- kidney problems
- liver problems
- diabetes
- epilepsy or seizures
- bipolar disorder (manic depression)
- a bleeding disorder

- a tendency to bleed or bruise easily
- restlessness and/or a need to move often
- eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Your doctor may want to take special care if you have any of these conditions.

Tell your doctor if you are receiving electroconvulsive therapy (ECT).

Tell your doctor if you are pregnant or plan to become pregnant.

If you are pregnant or plan to become pregnant you need to discuss with your doctor the risks and benefits of taking Celapram during pregnancy. Make sure your doctor and/or midwife know you are on Celapram. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

When taken during pregnancy, and particularly in the last 3 months of pregnancy, medicines like Celapram 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 symptoms usually begin during the first 24 hours after the baby is born. If your newborn baby has any of these symptoms, please contact your doctor immediately. If you take Celapram 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 Celapram so they can

advise you.

If used during pregnancy, Celapram should never be stopped abruptly.

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Like many other medicines, Celapram can pass into the breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Celapram when breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking Celapram.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop

You should also tell any health professional who is prescribing a new medication for you that you are taking Celapram.

Some medicines may interfere with Celapram. These include

- Monoamine Oxidase Inhibitors (MAOIs) e.g. moclobemide, phenelzine, tranylcypromine
- selegiline, a medicine used to treat Parkinson's disease
- pimozone
- linezolid, an antibiotic
- bupropion, a medicine helping to treat nicotine dependence
- other antidepressants including tricyclic antidepressants and other SSRIs e.g. imipramine, desipramine, fluoxetine, nortriptyline
- mefloquine, an anti-malaria medicine
- St John's Wort (*Hypericum perforatum*), a herbal remedy
- antipsychotic medicines and medicines for mental

health disorders e.g. risperidone, thioridazine, haloperidol, chlorpromazine, flupenthixol, zuclopenthixol and others

- some heart medication e.g. flecainide, propafenone, or some beta-blocker medicines such as metoprolol
- medicines used to treat reflux and ulcers e.g. omeprazole, lansoprazole, cimetidine, and esomeprazole
- medicines known to prolong bleeding e.g. aspirin or other non-steroidal anti-inflammatory agents (NSAIDs)
- Antifungal medicines e.g. fluconazole, voriconazole
- Some antibiotics e.g. azithromycin, clarithromycin, erythromycin, roxithromycin, amphotericin, gentamicin
- ticlopidine and warfarin, medicines used to prevent blood clots
- tramadol, a medicine used to relieve pain
- sumatriptan, a medicine used to treat migraines
- lithium, a medicine used to treat mood swings and some types of depression
- tryptophan, an amino acid
- diuretics, medicines that remove excess fluid
- carbamazepine, a medicine to help prevent seizures
- any other medicines that affect chemicals in the brain.

These medicines may be affected by Celapram or may affect how well it works. You may need to take different amounts of your medicines, or you may need to take different medicines.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Drugs that are known to affect the way the heart beats (for example some heart medicines, antibiotics) should be avoided while taking Celapram. If it is necessary for you to be on these medicines at the same time as Celapram, your doctor may perform an ECG test to check your heart rate and rhythm.

Your doctor or pharmacist have more information on medicines to be careful with or avoid while taking Celapram.

How to take Celapram

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual daily dose of Celapram is:

- For adults: a single oral dose of 20mg daily. The dose may be increased to a maximum of 40mg daily depending on your response and severity of depression.
- For elderly patients: starting with 10mg daily, the dose may be increased to a maximum of 20mg daily depending on your response or severity of depression.
- For patients with reduced liver function: the maximum recommended dose is 20mg daily.

Celapram should not be used in children and adolescents (under 18 years of age).

Your doctor may tell you to take different doses to these. If so, follow their instructions.

How to take it

Swallow the tablet(s) whole with a full glass of water.

When to take it

Take Celapram once daily. It does not matter if you take it in the morning or in the evening.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Celapram can be taken with or without food.

How long to take it

Continue to take Celapram even if it takes some time before you feel any improvement in your condition.

As with other medicines for the treatment of these conditions it may take a few weeks before you feel any improvement. Individuals will vary greatly in their response to Celapram. Your doctor will check your progress at regular intervals. Even when you feel well, you will usually have to take Celapram for several months or even longer to make sure the benefits will last.

Continue taking your medicine until your doctor tells you to stop, even if you begin to feel better.

The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return.

Do not stop taking this medicine suddenly.

If Celapram is stopped suddenly you may experience mild, but usually temporary, symptoms such as dizziness, pins and needles, sleep disturbances (vivid dreams, inability to sleep), feeling anxious or agitated, headaches, feeling sick (nausea), vomiting, sweating, tremor (shaking), feeling confused, feeling emotional or irritable, diarrhoea, visual disturbances, or fast or irregular heartbeats.

When you have completed your course of treatment, the dose of Celapram is gradually reduced over a couple of weeks rather than stopped abruptly.

Your doctor will tell you how to reduce the dosage so that you do not get these unwanted effects.

If you forget to take it

If you miss a dose and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally.

Otherwise, if it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Celapram

Things you must do

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Celapram.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Celapram.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Celapram. It may affect other medicines used during surgery.

If you are going to have any blood tests, tell your doctor that you are taking Celapram.

It may interfere with the results of some tests.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

Tell your doctor immediately if you have any suicidal thoughts or other mental or mood changes.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression 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, between 18 to 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know demonstrates any of the following warning signs of suicide-related behaviour while taking Celapram, contact a health care provider immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide

- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or new symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity or worsening of depression.

Tell your doctor immediately if you experience symptoms such as restlessness or difficulty in sitting or standing still.

These symptoms can occur during the first weeks of treatment.

Contact your doctor as soon as possible if you suddenly experience an episode of mania. Some patients may have bipolar disorder (manic depression) and may enter into a manic phase.

Mania may be characterised by a mood of overexcitement, over-activity and uninhibited behaviour, profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity.

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.

Things you must not do

Do not take Celapram to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking Celapram or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

If you stop taking Celapram suddenly, your condition may worsen or you may have unwanted side effects such as dizziness, nausea (feeling sick), headache, irritability, anxiety and difficulty sleeping.

Your doctor may want you to gradually reduce the amount of Celapram you take over several weeks or months before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Celapram affects you.

This medicine may cause dizziness, drowsiness and fatigue in some people and may affect alertness. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

After you have stopped taking Celapram, you should still be careful for 1 or 2 weeks because some of the medicine may still be in your blood stream.

Your doctor may suggest avoiding alcohol while you are being treated for depression. It is not advisable to drink alcohol while you are taking Celapram.

Older people may become confused when taking Celapram. Families and carers should be aware of this. Special care may be needed.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Celapram. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea (feeling sick)
- vomiting
- dizziness
- drowsiness, sleepiness
- agitation
- high or low blood pressure
- convulsions
- coma
- unconsciousness
- fast or slow or irregular heart beats
- tremor
- chest pain
- heart problems
- dilated pupils of the eyes

A condition called serotonin syndrome may occur that may show symptoms such as:

- high fever
- agitation
- confusion
- trembling
- abrupt contractions of muscles

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Celapram.

This medicine helps most people with depression, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Side effects observed with Celapram are in general mild and disappear after a short period of time. They are most frequent during the first one or two weeks of treatment and usually decrease in intensity and frequency with continued treatment.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- itching
- ringing or other persistent noise in the ears
- aching muscles or joint pain
- flu-like symptoms, fever, runny or blocked nose, sneezing, facial pressure or pain, coughing or sore throat
- dry mouth or taste change
- increased saliva
- decreased appetite or loss of appetite
- weight decrease or increase
- headache, migraine or dizziness
- difficulties sleeping
- drowsiness, sleepiness, fatigue or yawning
- a sense of indifference to everything
- stomach or bowel problems (e.g. nausea (feeling sick), vomiting, heartburn, indigestion, diarrhoea, constipation, or flatulence, stomach pain or discomfort)
- increased sweating
- tremor
- problems with menstrual periods
- Restlessness or difficulty keeping still
- sexual disturbances (problems with erection or ejaculation, decreased sexual drive and women may experience difficulties achieving orgasm).

Tell your doctor as soon as possible if you notice any of the following:

- Chest pain
- Shortness of breath
- fainting
- agitation anxiety, worsening of depression
- dizziness
- dizziness when you stand up due to low blood pressure
- decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or

feeling confused) which may be caused by SSRI antidepressants, especially in elderly patients

- abnormal liver function tests (increased amounts of liver enzymes in the blood)
- difficulty urinating or passing more urine than normal
- tingling or numbness of the hands or feet
- nervousness, confusion, problems with concentration, loss of memory
- unusual secretion of breast milk
- increased tendency to develop bruises
- rash, itching, patches of circumscribed swellings
- a fast heart rate or decrease in heart rate or irregular heartbeat
- unusual vaginal bleeding
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Before you start to take it' section for more information
- unusual bleeding, including bleeding from the stomach or bowel
- vision disturbances, blurred vision, eye pain or unusually dilated pupils

The above list includes more serious side effects that may require medical attention.

The symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or suicide. These symptoms may continue or get worse during the first one or two months of treatment until the full antidepressant effect of citalopram becomes apparent.

If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- worsening of your depression

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives)
- high fever, agitation, confusion, trembling and abrupt contractions of muscles (these symptoms may be signs of a rare condition called serotonin syndrome which has been reported with the combined use of antidepressants)
- mania (refer to *While you are taking Celapram* section)
- hallucinations
- seizures, tremors, movement disorders (involuntary movements of the muscles)
- vomiting blood or developing black or blood stained stools.
- fast, irregular heartbeat with feelings of dizziness, faintness, loss of consciousness or difficulty breathing
- thoughts of suicide

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you get any side effects when stopping Celapram treatment.

There is no evidence that Celapram

is addictive, however, you may get side effects if you suddenly stop taking it. Some such side effects could include:

- dizziness
- tingling or numbness of the hands or feet
- headache
- anxiety
- nausea.

These symptoms are generally not serious and disappear within a week or two.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

This medicine 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

The lists of side effects mentioned above are not complete. Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Celapram

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blisters they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Celapram, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Celapram or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What it look like

CELAPRAM tablets are white, oval shaped, engraved "CM" breakline "20" on one side and "G" on the other.

Celapram is available in blister packs of 28, 84 and 100 tablets.

Not all pack sizes may be marketed

Ingredients

Active ingredient:

Celapram contains 24.98 mg of citalopram hydrobromide as the active ingredient, corresponding to 20 mg citalopram base.

Inactive ingredients:

Celapram also contains:

- lactose
- maize starch
- microcrystalline cellulose
- povidone
- crospovidone
- magnesium stearate
- hypromellose
- macrogol
- titanium dioxide

Contains sulfites and sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Celapram is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of information

02 October 2023 (based on data sheet dated 10 August 2023).

CELAPRAM® is a Viatrix company trade mark.