

Celapram

citalopram hydrobromide

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Celapram.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Celapram against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Celapram is used for

Celapram is used to treat depression.

Celapram belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). They are thought to work by acting on chemicals in your brain called amines. These amines are involved in controlling mood.

Depression is longer lasting or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can 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 corrects this chemical imbalance and may help relieve the symptoms of depression.

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

Your doctor may have prescribed Celapram for another reason.

Celapram 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 a 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.

Do not take Celapram if you are allergic to medicines containing citalopram hydrobromide (e.g. Cipramil) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing, or difficulty breathing, swelling of the face, lips or tongue or

other parts of the body or rash, itching or hives on the skin.

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

- pimozide, a medicine used to treat mental disorders
- monoamine oxidase inhibitors (MAOI), which are also used for the treatment of depression.
- monoamine oxidase inhibitors such as selegiline which is used in the treatment of Parkinson's Disease

Do not take Celapram when you are taking a MAOI or when you have been taking a MAOI within the last 14 days.

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.

- the antibiotic linezolid
- Do not take Celapram when you are taking the antibiotic linezolid, or have recently stopped taking linezolid in the last 14-days.

Do not take Celapram if the expiry date (EXP) printed on the pack or bottle has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Celapram if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if:

- **you have allergies to any other medicines, foods, dyes or preservatives.**
- **you are pregnant or plan to become pregnant.**

Citalopram has been shown to reduce the quality of sperm in animal studies, which theoretically could affect fertility. If you are intending to start a family, ask your doctor for advice.

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

Make sure your doctor and/or midwife know you are on Celapram.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like Celapram may affect the general condition of your newborn baby and 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 this happens to your baby you should contact your doctor and/or midwife immediately.

Your doctor will discuss the possible risks and benefits of taking Celapram during pregnancy.

If used during pregnancy Celapram should never be stopped abruptly.

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

Do not take Celapram if you are breast-feeding unless you and your doctor have discussed the risks and benefits involved. It is not recommended that you breast-feed while taking Celapram as it is excreted in breast milk.

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

- Congenital long QT syndrome or other heart conditions. Your doctor may occasionally need to check your heart beat and rhythm with an ECG test
- illnesses which require you to have regular blood test
- A tendency to bleed or bruise easily
- bipolar disorder (manic depression)
- diabetes
- a history of seizures or fits
- liver disease
- kidney disease
- restlessness and/or a need to move often
- raised intraocular pressure (fluid pressure in the eye), or if you are a risk of angle-closure glaucoma.
- epilepsy

Tell your doctor if you are receiving electroconvulsive therapy.

If you are lactose intolerant, contact your doctor before taking Celapram.

Celapram tablets contain lactose.

Do not give Celapram to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Celapram can be given to elderly patients over 65 years of age with a reduced dose.

The effects of Celapram in elderly patients are similar to that in other patients.

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

Some medicines and Celapram may interfere with each other. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat depression.

Do not take Celapram with MAOIs.

Celapram can only be started after you have stopped taking:

- tranylcypromine and phenelzine for at least 14 days
- moclobemide for at least 1 day
- other antidepressants, including other SSRIs and tricyclic antidepressants such as imipramine, despiramine
- medicines used to treat mental illnesses such as schizophrenia, depression and mood swings, including antipsychotics and lithium
- linezolid, an antibiotic
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, which are used to treat both pain and inflammation
- sumatriptan, a medicine used to relieve migraines
- tryptophan, an amino acid found in sports and dietary supplements
- ketoconazole, itraconazole, fluconazole, medicines taken to treat fungal infections
- macrolide antibiotics such as erythromycin and clarithromycin
- warfarin, a medicine used to prevent blood clots
- carbamazepine, a medicine used to treat convulsions
- cimetidine and omeprazole, medicines used to treat reflux and stomach ulcers
- St John's Wort (Hypericum perforatum), a herbal remedy used for depression
- tramadol, a medicine used for pain relief
- selegiline, a medicine used to treat Parkinson's disease

- beta-blockers, medicines used to treat high blood pressure and other heart problems such as metoprolol
- antiarrhythmics, medicines used to treat an irregular heart beat
- digoxin, a medicine used to treat heart failure or to control a fast irregular heart beat
- any other medicines for depression, anxiety, obsessive-compulsive disorder or premenstrual dysphoric disorder.

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

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, asthma medicines, antihistamines) 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 and 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 and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

The dose varies from person to person.

The standard dose for adults for this medicine is between 20 mg and 40 mg (one to two tablets) per day.

Your doctor may gradually increase this dose depending on how you respond to this medicine.

The recommended starting dose in elderly patients is 10 mg (half a tablet) per day but may be increased to a maximum of 20 mg (one tablet) per day by your doctor if needed.

If you have liver problems, or are taking medicines such as cimetidine or omeprazole, the recommended starting dose is 10mg (half a tablet) per day. The dose can be increased to a maximum of 20mg (one tablet) per day.

Your doctor may have prescribed a different dose. If you have been prescribed or are currently taking doses of Celapram greater than 40mg, talk to your doctor about reducing the dose.

Celapram is not recommended for use in children and adolescents below 18 years of age.

Its safety and effectiveness in this age group has not been established.

How to take it

Swallow the tablets as a single daily dose with a glass of water.

Celapram 20 mg and 40 mg tablets can be divided in half if advised by your doctor or pharmacist.

When to take it

Take Celapram 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 to remember when to take it.

Celapram can be taken with or without food, either in the morning or evening.

How long to take it

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

Most medicines of this type take time to work, so do not be discouraged if you do not feel better right away. The treatment of depression may take at least six months.

Continue taking your medicine for as long as your doctor tells you, 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 are less than 12 hours late in taking a tablet, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

If you are more than 12 hours late, then skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do or you have any questions about this, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think 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, fast or slow heart beat or changes in heart rhythm, decreased or increased blood pressure, tremor (shaking), agitation, dilated pupils of the eyes, drowsiness, sleepiness, lethargy, sweating, blueish discolouration of the skin and an increase in rate of breathing. Convulsions or coma may occur. A condition called serotonin syndrome may occur with high fever, agitation, confusion, trembling and abrupt contractions of muscles.

While you are taking Celapram

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Celapram.

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

Persons taking Celapram may be more likely to think about killing themselves or actually trying to do so, especially when Celapram is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone taking Celapram

who talks about or shows signs of killing him or herself.

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 in children, adolescents and young adults under 25 years of age, and you have not used antidepressant medicines before.

Contact your doctor or a mental health professional right away, or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- 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, agitation or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously. Family and carers of people taking Celapram also need to monitor for the above symptoms.

Do not stop taking this medicine or change the dose without consulting your doctor, even if you experience increased anxiety at the beginning of treatment.

At the beginning of treatment, some patients may experience increased anxiety which will disappear during continued treatment.

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 immediately if you experience episodes of mania.

Some people with manic-depressive illness (bipolar disorder) may enter a

manic phase. Symptoms of mania include rapidly changing thoughts or ideas, excessive physical activity and excessive restlessness.

Visit your doctor regularly so they can check on your progress.

If you become pregnant while taking Celapram, tell your doctor immediately. Do not stop taking your tablets until you have spoken to your doctor.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking Celapram.

Things you must not do

Do not use Celapram to treat any other conditions unless your doctor tells you to.

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

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

Do not let yourself run out of Celapram over weekends or holidays.

If you stop Celapram suddenly, you may get unwanted side effects, such as dizziness, headache and nausea.

Your doctor will tell you how to gradually reduce the amount of Celapram you are taking before stopping completely. This is usually done slowly over one to two weeks.

Things to be careful of

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

Celapram may cause dizziness, visual disturbances or drowsiness in some people. If you experience any of these, do not drive, operate machinery or do anything else that could be dangerous.

Avoid alcohol while you are taking this medicine.

It is not advisable to drink alcohol while you are being treated for depression.

Side effects

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

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

All medicines 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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor 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
- increased sweating
- sleepiness or drowsiness, fatigue, yawning
- dizziness
- diarrhoea, constipation, flatulence, indigestion, stomach pain or discomfort
- increase saliva or dry mouth, taste disturbance
- nausea (feeling sick) or vomiting
- loss of appetite or increased appetite, weight gain or weight loss
- a sense of indifference to everything
- sexual disturbances (decreased sexual drive, problems with orgasm, problems with ejaculation or erection)

- migraine, headache
- restlessness
- unable to sit or stand still for extended periods of time
- problems with menstrual periods.

These are the more common yet mild side effects of Celapram. Some of these may occur within the first two weeks of treatment and disappear after a short period of time.

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

- chest pain
- a fast heart rate or decrease in heart rate or irregular heartbeat
- shortness of breath
- fainting
- nervousness, confusion, hallucinations, loss of memory
- blurred vision
- dizziness on standing up, especially when getting up from a sitting or lying position
- low sodium levels 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
- worsening depression, anxiety, agitation, aggressive behaviour
- increased tendency to develop bruises
- passing more urine than normal or difficulty passing urine
- unusual bleeding, including bleeding from the stomach or bowel
- tingling or numbness of the hands or feet

These side effects listed above are serious and may need urgent medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- thoughts of suicide
- serious allergic reaction (symptoms of an allergic reaction

may include shortness of breath, wheezing or trouble breathing; swelling of the face, lips, tongue or other parts of the body, sometimes with itching, skin rash)

- 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)
- tremors, movements disorders (involuntary movements of the muscles)
- fast, irregular heart beat with feelings of dizziness or difficulty breathing.

The above list includes very serious side effects, which are uncommon or rare. You may need urgent medical attention or hospitalisation.

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

An increased risk of bone fractures has been observed in patients taking medicines like Celapram.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people.

After taking Celapram

Storage

Keep Celapram 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.

Keep your tablets in the pack or bottle until it is time to take them.

If you take the tablets out of the pack or bottle 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 Celapram in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Celapram, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Celapram is available in 3 strengths:

- 10 mg - round, white, film-coated tablet marked "CM" over "10" on one side and "G" on the other. Each pack contains 28 tablets.
- 20 mg - oval, white, scored film-coated tablet marked "CM breakline 20" on one side and "G" on the other. Each pack and bottle contains 28 tablets.
- 40 mg - oval, white, scored, film-coated tablet marked "CM breakline 40" on one side and "G" on the other. Each pack contains 28 tablets.

Ingredients

The active ingredient in Celapram is citalopram hydrobromide.

Celapram tablets contain 10 mg, 20 mg or 40 mg of citalopram (as citalopram hydrobromide).

The tablets also contain the following inactive ingredients:

- maize starch
- lactose monohydrate
- microcrystalline cellulose
- povidone
- crospovidone
- macrogol 4000
- magnesium stearate

- hypromellose
- titanium dioxide (E171).

Celapram contains sugars (as lactose). The tablets are gluten free.

Supplier

Celapram is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

- Celapram 10 mg
 - AUST R 93542 (blister pack)
- Celapram 20 mg
 - AUST R 82904 (blister pack)
 - AUST R 82905 (bottle)
- Celapram 40 mg
 - AUST R 93543 (blister pack)

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