

# Celapram

contains the active ingredient 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.

**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.

### Before you take Celapram

#### ***When you must not take it***

**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.**

Some symptoms of an allergic reaction include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

**Do not take Celapram if you are taking pimozone (Orap), a medicine for schizophrenia.**

Combining Celapram and pimozone may lead to electrical disturbances in the heart.

**Do not take Celapram if you are taking another medicine for depression known as a monoamine oxidase inhibitor (MAOI).**

Celapram can only be started after you have stopped taking:

- \* tranylcypromine (Parnate) and phenelzine (Nardil) for at least 14 days
- \* moclobemide (e.g. Aurorix, Arima) for at least 1 day.

If you do take Celapram while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

**Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a**

MAOI.

**Do not give Celapram to children and adolescents under 18 years of age.**

Celapram is not recommended for children and adolescents below 18 years of age, as its safety and effectiveness has not been established in this age group.

**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 are allergic to any other medicines, foods, dyes or preservatives.**

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

There have been reports that babies exposed to some antidepressants like Celapram during the third trimester of pregnancy may develop complications after birth. Your doctor will discuss the possible risks and benefits of taking Celapram during pregnancy.

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Celapram passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Celapram when breastfeeding.

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

- \* mania and/or bipolar disorder (manic-depressive illness)
- \* history of suicide-related events (suicidal thoughts or actions)
- \* heart problems, including a slow heart rate
- \* diabetes
- \* epilepsy
- \* liver problems
- \* kidney problems
- \* bleeding disorders
- \* lactose or galactose intolerance, Lapp lactase insufficiency, glucose or galactose malabsorption (Celapram tablets contain lactose).

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

**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 (Parnate) and phenelzine (Nardil) for at least 14 days
- moclobemide (e.g. Aurorix, Arima) for at least 1 day
- \* other antidepressants, including other SSRIs and tricyclic antidepressants such as imipramine (e.g. Tofranil)
- \* medicines used to treat mental illnesses such as schizophrenia,

depression and mood swings, including antipsychotics and lithium (e.g. Lithicarb)

- \* Non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, which are used to treat both pain and inflammation
- \* sumatriptan (e.g. Imigran), a medicine used to relieve migraines
- \* tryptophan, an amino acid found in sports and dietary supplements
- \* ketoconazole (Nizoral), itraconazole (Sporanox), medicines taken to treat fungal infections
- \* macrolide antibiotics such as erythromycin (e.g. EES) and clarithromycin (e.g. Klacid)
- \* carbamazepine (e.g. Tegretol, Teril), a medicine used to control fits
- \* cimetidine (e.g. Tagamet, Magicul) and omeprazole (e.g. Losec, Acimax), medicines used to treat reflux and stomach ulcers
- \* St John's Wort (Hypericum perforatum), a herbal remedy used for depression
- \* tramadol (e.g. Tramal), aspirin and other NSAIDs (non-steroidal anti-inflammatory drugs), medicines used for pain relief
- \* beta-blockers, medicines used to treat high blood pressure and other heart problems such as metoprolol (e.g. Betaloc, Minax)
- \* 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.

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.

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

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

Celapram.

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## **How to take Celapram**

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**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 usual starting dose is 20 mg once a day. Your doctor may gradually increase this dose depending on how you respond to this medicine. The maximum dose is 60 mg a day.

Some people, including the elderly, may need smaller doses. The maximum dose for elderly people is 40 mg a day.

**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***

**Keep taking Celapram for as long as your doctor recommends.**

The length of treatment with Celapram will depend on how quickly your symptoms improve.

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.

**Do not stop taking this medicine without checking first with your doctor.**

## ***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.

If you take too much Celapram, you may feel drowsy, tired, have fits, a fast heart rate, nausea (feeling sick), vomiting, tremors and sweating.

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## **While you are taking Celapram**

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### ***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.

**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.

**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, feelings like pins and needles, sleep disturbances, anxiety, headache, nausea (feeling sick), vomiting, sweating, diarrhoea (loose stools), tremor, confusion, palpitations, visual disturbances, feeling emotional or irritable.

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.

**It is recommended you do not drink alcohol while taking Celapram tablets.**

**If your doctor has changed your treatment to a MAOI (monoamine oxidase inhibitor) antidepressant, wait at least 14 days after stopping Celapram before starting the MAOI medicine.**

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## Side effects

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**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:**

- \* increased sweating
- \* tremor
- \* drowsiness, dizziness
- \* diarrhoea, constipation
- \* dry mouth, altered taste sensation
- \* nausea (feeling sick)
- \* weight gain or weight loss
- \* sexual problems
- \* visual disturbances

- \* migraine, headache
- \* restlessness and/or the need to move around often
- \* unable to sit or stand still for extended periods of time
- \* passing more urine than normal or difficulty passing urine
- \* females: 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:**

- \* confusion, hallucinations, loss of memory
- \* dizziness on standing up, especially when getting up from a sitting or lying position
- \* stomach pain with nausea and vomiting, vomiting blood, sometimes with blood in the bowel motions
- \* anxiety, nervousness, agitation, aggressive behaviour
- \* mood of excitement, over-activity and uninhibited behaviour
- \* signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- \* increased sensitivity to the sun with symptoms of sunburn occurring more quickly than normal
- \* abnormal bruising or bleeding under the skin
- \* yellowing of the skin and/or eyes, also called jaundice
- \* bleeding nose occurring more frequently than usual
- \* slow or fast heart beat.

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
- \* chest pain, very fast heart beat

- \* shortness of breath, wheezing or trouble breathing; swelling of the face, lips, tongue or other parts of the body, sometimes with itching, skin rash
- \* convulsions, fits or seizures.

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.**

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

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## After taking Celapram

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### 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 degrees 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.**

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## Product description

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### **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
- \* microcrystalline cellulose
- \* povidone
- \* crospovidone
- \* macrogol 4000
- \* magnesium stearate
- \* hypromellose
- \* titanium dioxide (E171).

The tablets are gluten free.

### **Manufacturer**

Celapram is made in Australia by:

Alphapharm Pty Limited  
(ABN 93 002 359 739)  
Chase Building 2  
Wentworth Park Road  
Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

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)

This leaflet was prepared on  
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