

APX-CITALOPRAM

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APX-CITALOPRAM?

APX-CITALOPRAM contains the active ingredient citalopram. APX-CITALOPRAM is used to treat depression. For more information, see Section [1. Why am I using APX-CITALOPRAM?](#) in the full CMI.

2. What should I know before I use APX-CITALOPRAM?

Do not use if you have ever had an allergic reaction to citalopram or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APX-CITALOPRAM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APX-CITALOPRAM and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APX-CITALOPRAM?

- Your doctor will decide what dose you will receive.
- The standard dose for adults for this medicine is between 20 mg and 40 mg (one to two tablets) per day.

More instructions can be found in Section [4. How do I use APX-CITALOPRAM?](#) in the full CMI.

5. What should I know while using APX-CITALOPRAM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APX-CITALOPRAM.• If you become pregnant while taking APX-CITALOPRAM, tell your doctor immediately.• Tell your doctor immediately if you have thoughts about killing yourself.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage without telling your doctor.• Do not give the tablets to anyone else, even if they have the same condition as you.• Do not let yourself run out of medicine over the weekend or on holidays.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APX-CITALOPRAM affects you.• APX-CITALOPRAM may cause visual disturbance (such as blurred vision), nausea, fatigue, and dizziness in some people, especially early in the treatment. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• It is not advisable to drink alcohol while you are being treated for depression.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place below 25°C, away from moisture, heat or sunlight.• Keep your tablets in the original packaging, in a safe place, away from children.

For more information, see Section [5. What should I know while using APX-CITALOPRAM?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: decreased appetite or loss of appetite, dry mouth diarrhoea, nausea, sleeplessness, fatigue, sleepiness or drowsiness, yawning, increased sweating, sexual disturbances. **Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:** thoughts of harming yourself or thoughts of suicide, serious allergic reaction, high fever, agitation, confusion, trembling and abrupt contractions of muscles, mania, hallucinations, seizures, tremors, movement disorders, fast, irregular heartbeat. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APX-CITALOPRAM

Active ingredient(s): Citalopram hydrobromide (sigh-TALO-pram high-dro-BRO-mide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using APX-CITALOPRAM. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APX-CITALOPRAM.**

Where to find information in this leaflet:

- [1. Why am I using APX-CITALOPRAM?](#)
- [2. What should I know before I use APX-CITALOPRAM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APX-CITALOPRAM?](#)
- [5. What should I know while using APX-CITALOPRAM?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APX-CITALOPRAM?

APX-CITALOPRAM contains the active ingredient citalopram hydrobromide. APX-CITALOPRAM belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). They are thought to work by their actions on brain chemicals called amines which are involved in controlling mood.

APX-CITALOPRAM is used to treat depression.

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.

APX-CITALOPRAM corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor, however, may prescribe it for another purpose.

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

2. What should I know before I use APX-CITALOPRAM?

Warnings

Do not use APX-CITALOPRAM if:

- You are allergic to citalopram hydrobromide, or any of the ingredients listed at the end of this leaflet.
- you have a condition called 'congenital long QT syndrome'. At high doses, APX-CITALOPRAM 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 APX-CITALOPRAM.
- Always check the ingredients to make sure you can use this medicine.
- The packaging is torn or shows signs of tampering

Check with your doctor if you:

- you have allergies to any other substances such as foods, preservatives, or dye. 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, or rash, itching or hives on the skin.
- are pregnant or intend to become pregnant.
- have any other medical conditions.
- take any medicines for any other condition.
- are lactose intolerant, as APX-CITALOPRAM tablets contain lactose.

If you have, or have had any of the following medical conditions, tell your doctor before starting APX-CITALOPRAM

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Do not take APX-CITALOPRAM at the same time as the following other medicines:

- pimozide, a medicine used to treat mental disorders
- monoamine oxidase inhibitors (MAOIs), such as phenelzine, tranylcypromine and moclobemide which are also used for the treatment of depression.
- monoamine oxidase inhibitors such as linezolid which is an antibiotic and selegiline which is used in the treatment of Parkinson's Disease.

One day must elapse after you have finished taking moclobemide before you start taking APX-CITALOPRAM. If you have taken any other MAOI you will need to wait 14 days. After stopping APX-CITALOPRAM you must allow 14 days before taking any MAOI including moclobemide.

Taking APX-CITALOPRAM 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 APX-CITALOPRAM after the MAOI has been stopped.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Citalopram hydrobromide 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 APX-CITALOPRAM 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 APX-CITALOPRAM.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like APX-CITALOPRAM 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.

If you take APX-CITALOPRAM 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 APX-CITALOPRAM so they can advise you. If used during pregnancy APX-CITALOPRAM should never be stopped abruptly.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed. Do not take APX-CITALOPRAM 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 APX-CITALOPRAM as it is excreted in breast milk.

APX-CITALOPRAM use in children and adolescents

- Do not give APX-CITALOPRAM to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

APX-CITALOPRAM use in the elderly

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

The effects of APX-CITALOPRAM in elderly patients are similar to those in other patients.

3. What if I am taking other medicines?

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

Some medicines may interfere with APX-CITALOPRAM and affect how it works.

- linezolid, an antibiotic
- lithium, used to treat mood swings and some types of depression
- tricyclic antidepressants, e.g. imipramine, desipramine
- some heart medications, such as beta-blockers (e.g. metoprolol) or antiarrhythmics
- sumatriptan, used to treat migraines

- medicines used to treat reflux and ulcers, such as cimetidine and omeprazole
- medicines known to prolong bleeding, e.g. aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- warfarin, a medicine used to prevent blood clots
- St John's Wort (*Hypericum perforatum*), a herbal remedy
- Ketoconazole, flucanazole and itraconazole, medicines used to treat fungal infections
- macrolide antibiotics, e.g. erythromycin and clarithromycin
- carbamazepine, a medicine used to treat convulsions
- selegiline, a medicine used to treat Parkinson's disease
- tryptophan, an amino acid
- antipsychotics, a class of medicines used to treat certain mental and emotional conditions
- any other medicines for depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder.

These medicines may be affected by APX-CITALOPRAM, or may affect how well it works. You may need to use different amounts of your medicines or 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 APX-CITALOPRAM. If it is necessary for you to be on these medicines at the same time as APX-CITALOPRAM, your doctor may perform an ECG test to check your heart rate and rhythm.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking APX-CITALOPRAM.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APX-CITALOPRAM.

4. How do I use APX-CITALOPRAM?

How much to take

- Your doctor will decide what dose you will receive.
- The standard dose for adults for this medicine is between 20 mg and 40 mg (one to two tablets) per day.
- 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.
- tramadol and similar medicines, used to relieve pain

- If you have liver problems, or are taking medicines such as cimetidine and 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 APX-CITALOPRAM greater than 40mg, talk to your doctor about reducing the dose.
- Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.
- Follow the instructions provided and use APX-CITALOPRAM until your doctor tells you to stop.

When to take APX-CITALOPRAM

- Take APX-CITALOPRAM as a single dose either in the morning or in the evening.

- Take APX-CITALOPRAM with or without food

How to take APX-CITALOPRAM

- Swallow the tablets whole with a full glass of water.
- Do not chew APX-CITALOPRAM tablets.

How long to take it

Continue to take APX-CITALOPRAM 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 APX-CITALOPRAM. Your doctor will check your progress at regular intervals.

The duration of treatment may vary for each individual, but is usually at least 6 months.

In some cases, the doctor may decide that longer treatment is necessary.

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 APX-CITALOPRAM 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 APX-CITALOPRAM 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 use APX-CITALOPRAM

APX-CITALOPRAM should be used regularly at the same time each day. If you miss your dose at the usual time, and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally.

If it is almost time for your next dose, 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, ask your doctor or pharmacist. Do not chew APX-CITALOPRAM tablets.
- If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you use too much APX-CITALOPRAM

If you think that you have used too much APX-CITALOPRAM, you may need urgent medical attention.

Symptoms of an overdose may include nausea (feeling sick), vomiting, dizziness, fast or slow heart beat or change 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.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APX-CITALOPRAM?

Things you should do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking APX-CITALOPRAM, tell your doctor immediately.

Persons taking APX-CITALOPRAM may be more likely to think about killing themselves or actually trying to do so, especially when APX-CITALOPRAM 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 using APX-CITALOPRAM who talks about or shows signs of killing him or herself.

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, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

Patients and care givers should pay attention for any of the following warning signs of suicide-related behaviour while taking APX-CITALOPRAM. Tell your doctor 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.

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.

Call your doctor straight away if you:

- become pregnant while taking APX-CITALOPRAM
- have thoughts about killing yourself or if you are close to or care for someone using APX-CITALOPRAM who talks about or shows signs of killing him or herself
- suddenly experience an episode of mania

- experience symptoms such as restlessness or difficulty in sitting or standing still. These symptoms can occur during the first weeks of treatment.
- suddenly experience an episode of mania. Some patients with bipolar disorder (manic depression) may enter into a manic phase. This is characterised by 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.

Remind any doctor, dentist or pharmacist you visit that you are using APX-CITALOPRAM.

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Things you should not do

- Do not give the tablets to anyone else, even if they have the same condition as you.
- Do not take APX-CITALOPRAM to treat any other complaints unless your doctor tells you to.
- Do not stop taking APX-CITALOPRAM, or lower the dosage, without checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.

Suddenly stopping APX-CITALOPRAM may cause unwanted discontinuation symptoms such as dizziness, headache and nausea. Your doctor will tell you when and how APX-CITALOPRAM should be discontinued. Your doctor will gradually reduce the amount you are using, usually over a period of one to two weeks, before stopping completely.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APX-CITALOPRAM affects you.

It may cause nausea, fatigue and dizziness in some people, especially early in the treatment. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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

Store it in a cool dry place below 25°C away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

It helps most people with depression, but it may have unwanted side effects in a few people.

The side effects of APX-CITALOPRAM are, in general, mild and disappear after a short period of time.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 • increased saliva or dry mouth, taste disturbance • loss of appetite or increased appetite, weight decrease or weight increase • diarrhoea, constipation, flatulence, indigestion, stomach pain or discomfort • dizziness • nausea (feeling sick) or vomiting • migraine, headache • sleepiness or drowsiness, fatigue, yawning • a sense of indifference to everything • sexual disturbances (decreased sexual drive, problems with orgasm; problems with ejaculation or erection) • problems with menstrual periods • Restlessness or difficulty keeping still 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • chest pain • a fast heart rate or decrease in heart rate or irregular heartbeat • shortness of breath • fainting • dizziness when you stand up due to low blood pressure • blurred vision • low sodium levels in the blood (the symptoms are feeling sick and unwell with weak muscles or 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

Serious side effects	What to do
<p>feeling confused) which may be caused by SSRI antidepressants, especially in elderly patients</p> <ul style="list-style-type: none"> • increased tendency to develop bruises • unusual bleeding, including bleeding from the stomach or bowel • heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy and breastfeeding' in section 2 for more information • passing more urine than normal or problems when urinating • tingling or numbness of the hands or feet • nervousness, confusion, problems with concentration, loss of memory • agitation, anxiety, worsening of depression. • an increased risk of bone fractures has been observed in patients taking medicines like APX-CITALOPRAM. • thoughts of suicide • 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) • tremors, movement disorders (involuntary movements of the muscles). • fast, irregular heartbeat with feelings of dizziness or difficulty breathing • high prolactin concentration in the blood which may be caused by SSRI antidepressants 	<p>these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APX-CITALOPRAM contains

Active ingredient (main ingredient)	APX-CITALOPRAM 20 mg tablets 20 mg citalopram (as hydrobromide) per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • crospovidone • lactose monohydrate • magnesium stearate • povidone • maize starch • Opadry White complete film coating system Y-1-7000
Potential allergens	APX-CITALOPRAM tablets contain sugars as lactose. If you are lactose intolerant, contact your doctor before taking APX-CITALOPRAM.

Do not take this medicine if you are allergic to any of these ingredients.

What APX-CITALOPRAM looks like

APX-CITALOPRAM 20mg: white, oval, film coated tablet marked C | A on one side and blank on the other. Available in blister packs or bottles of 28 tablets.

Blister Pack AUST R 337470
Bottle AUST R 337471

Who distributes APX-CITALOPRAM

Arrotex Pharmaceuticals Pty. Ltd.
15-17 Chapel Street
Cremorne VIC 3121
Ph: 1800 195 055

This leaflet was prepared in June 2023.