

# APX-CITALOPRAM

*citalopram hydrobromide*

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## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about APX-CITALOPRAM. It does not contain all the available 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 APX-CITALOPRAM against the benefits they expect it will have for you.

**Talk to your doctor or pharmacist if you have any concerns about taking this medicine.**

**Keep this leaflet with your medicine.**

You may need to read it again.

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### What APX-CITALOPRAM is used for

APX-CITALOPRAM contains the active ingredient citalopram (as citalopram hydrobromide) and is used to treat depression.

It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

**Ask your doctor if you have any questions about why APX-CITALOPRAM has been prescribed for you.**

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. 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.

Citalopram corrects this chemical imbalance and may help relieve the symptoms of depression.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed APX-CITALOPRAM for another reason.

There is no evidence that it is addictive.

However, if you suddenly stop taking it, you may get side effects.

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

#### *Use in children and adolescents*

**Do not give APX-CITALOPRAM to children and adolescents under 18 years of age.**

APX-CITALOPRAM is not recommended for use in children and adolescents under 18 years of age as the safety and efficacy in this age group has not been established.

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### Before you take it

*When you must not take it*

**Do not take APX-CITALOPRAM if you have a heart condition called 'congenital long QT syndrome'. At high doses, APX-CITALOPRAM can cause changes in the way your heart beats.**

**See your doctor immediately if you experience an irregular heartbeat, shortness of breath, dizziness or fainting while taking APX-CITALOPRAM.**

**Do not take APX-CITALOPRAM if you are allergic to medicines containing citalopram or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may 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 APX-CITALOPRAM if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking an MAOI.**

Taking APX-CITALOPRAM with MAOI 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.

**Do not take APX-CITALOPRAM if you are taking linezolid**, used in some serious bacterial infections

**Do not take APX-CITALOPRAM if you are taking another medicine for psychotic disorder called pimozone.**

If you take APX-CITALOPRAM while you are on pimozone, you may experience irregular pulses/heart beats.

**Do not take the herbal remedy St. John's wort (hypericum perforatum) at the same time as taking APX-CITALOPRAM.**

**Do not take APX-CITALOPRAM if the expiry date (Exp.) printed on the pack has passed.**

It may not work as well if you do.

**Do not take APX-CITALOPRAM 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.**

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 used during pregnancy, APX-CITALOPRAM should never be stopped abruptly.

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

APX-CITALOPRAM passes into breastmilk and may affect your baby. Your doctor will discuss the risks and benefits of taking APX-CITALOPRAM when breastfeeding.

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

- A heart condition called 'congenital long QT syndrome'. Your doctor may need to check your heart beat and rhythm periodically using an ECG test. The ECG test provides a record of the electrical activity of the heart
- epilepsy or seizures
- diabetes
- restlessness and/or a need to move often
- liver disease
- kidney disease
- heart disease
- problems with blood clotting
- illnesses which require you to have regular blood tests
- mania and/or bipolar disorder (manic/depressive illness).
- Raised intraocular pressure (fluid pressure in the eye), or if you are at risk of angle-closure glaucoma.

**Tell your doctor if you are receiving electroconvulsive therapy.**

**If you are lactose intolerant, contact your doctor before taking APX-CITALOPRAM.**

**If you have not told your doctor about any of the above, tell them before you start taking APX-CITALOPRAM.**

*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 may be affected by APX-CITALOPRAM or may affect how well it works. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression. You should stop taking MAOIs at least two weeks before starting APX-CITALOPRAM
- pimozone, a medicine used to treat psychotic disorders (disturbances in thinking, feelings and behaviour)
- tryptophan, contained in some multivitamin and herbal preparations
- St. John's wort, a herbal remedy
- sumatriptan, used to treat migraine
- metoprolol, a medicine used to treat high blood pressure
- medicines used to treat reflux and ulcers including cimetidine and omeprazole
- selegiline, a medicine used to treat Parkinson's disease
- warfarin, used to prevent blood clots
- lithium, used to treat mood swings and some types of depression
- linezolid, an antibiotic
- carbamazepine, used to treat epilepsy
- tramadol, a medicine used to relieve pain
- sumatriptan and similar medicines used to treat migraines and cluster headaches
- some medicines used to treat fungal infections including ketoconazole and itraconazole
- macrolide antibiotics used to treat infections such as erythromycin and clarithromycin
- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (NSAIDs)

- antipsychotics, medicines used to treat certain mental and emotional conditions
- other medicines to treat depression, anxiety, obsessive-compulsive disorder or premenstrual dysphoric disorder.
- tricyclic antidepressants e.g. imipramine, desipramine.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

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 or antihistamines) should be avoided while taking APX-CITALOPRAM. If it is necessary to be on one of these medicines at the same time as APX-CITALOPRAM, your doctor may need to 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 APX-CITALOPRAM.

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## How to take it

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### *How much to take*

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

The dose varies from patient to patient.

The usual starting dose is 20 mg (one tablet) per day. Your doctor may increase the dose slowly over several weeks depending on how you respond to this medicine. The

maximum recommended dose is 40 mg (two tablets) per day.

The starting dose in elderly patients is 10 mg (half a tablet) per day and the maximum recommended dose is 20 mg (one tablet) per day.

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

**Your doctor may have prescribed a different dose.**

**If you have been prescribed or are currently taking more than 40 mg of APX-CITALOPRAM a day, 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 they give you.**

If you take the wrong dose, APX-CITALOPRAM may not work as well and your condition may not improve.

### *How to take it*

**Swallow the tablets with a glass of water.**

**APX-CITALOPRAM should be taken either in the morning or evening, with or without food.**

You will not feel the full benefit of APX-CITALOPRAM straight away. Individuals will vary greatly in their response to APX-CITALOPRAM. Your doctor will check your progress at regular intervals.

### *If you forget to take it*

**If you miss a dose and remember in less than 12 hours, take it straight away, and then continue as normal the next day.**

**Otherwise, skip the dose you missed, but be sure to take the next day's dose when it is due.**

**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.**

### *How long to take it*

To properly control your condition, APX-CITALOPRAM must be taken exactly as your doctor has prescribed. If you do not follow your doctor's instructions, you may not get relief from your depression.

**Keep taking APX-CITALOPRAM for as long as your doctor recommends.**

**Do not stop taking it even if you begin to feel better, unless you are told to do so by your doctor.**

If you suddenly stop taking your medicine, you may experience mild, but usually temporary, symptoms such as dizziness, feelings like pins and needles, sleeping problems (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), vomiting, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, or fast or irregular heartbeats.

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

**Never change the dose of your medicine without talking to your doctor first.**

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

**You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or**

experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

*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 APX-CITALOPRAM. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of overdosage may include nausea (feeling sick), vomiting, sweating, drowsiness, blue discolouration of the skin, convulsions or fits, unconsciousness, fast heart beats, tremor, agitation, dilated pupils of the eyes and sleepiness. Convulsions or coma may occur.

A condition called serotonin syndrome may occur, with high fever, agitation, confusion, trembling and abrupt contraction of muscles.

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## While you are taking it

*Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking APX-CITALOPRAM.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking APX-CITALOPRAM.**

**Tell your doctor immediately if you become pregnant while taking APX-CITALOPRAM.**

**Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or**

**care for someone taking APX-CITALOPRAM who talks about or shows signs of killing him or herself.**

People taking APX-CITALOPRAM may be more likely to think about killing themselves or actually try to do so, especially when APX-CITALOPRAM is first started or the dose is changed.

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 during the first one to two months of taking APX-CITALOPRAM until the medicine starts to work completely. 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.

**If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking APX-CITALOPRAM, contact a doctor immediately, or go to the nearest hospital for treatment:**

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

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

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

All talk of suicide or violence must be taken seriously.

**Tell your doctor immediately if you experience episodes of mania including a lot of rapidly changing thoughts or ideas, excessive physical activity and excessive restlessness.**

Some patients with manic-depressive illness may enter a manic phase and experience these symptoms.

*Things you must not do*

**Do not use APX-CITALOPRAM to treat any other conditions unless your doctor tells you to.**

**Do not suddenly stop taking APX-CITALOPRAM or lower the dose without checking with your doctor.**

Stopping APX-CITALOPRAM suddenly may cause discontinuation symptoms such as dizziness, nausea and headache. When you have completed your course of treatment, the dose of APX-CITALOPRAM should be gradually reduced over a couple of weeks.

**Do not give APX-CITALOPRAM to anyone else, even if they have the same condition as you.**

*Things to be careful of*

**Be careful driving or operating machinery until you know how APX-CITALOPRAM affects you.** APX-CITALOPRAM may cause drowsiness, dizziness or lightheadedness in some people. Make sure you know how you react to APX-CITALOPRAM before you drive a car or operate machinery.

APX-CITALOPRAM has not been shown to increase the effects of alcohol. However, your doctor may suggest avoiding alcohol while you are being treated for depression.

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## Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APX-CITALOPRAM.**

APX-CITALOPRAM 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.

**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 a 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
- increase or decrease in appetite
- weight decrease or increase
- nausea or vomiting
- diarrhoea or constipation
- increased flatulence (wind)
- headache or migraine
- yawning
- dizziness
- sleepiness or drowsiness, tiredness
- a sense of indifference to everything
- sexual disturbances (decreased sex drive, problems with orgasm, erection or ejaculation)
- problems with menstrual period.
- Restlessness or difficulty in keeping still

**Tell your doctor immediately if you notice any of the following:**

- chest pain
- slow, fast or irregular heart beat
- Shortness of breath
- dizziness when you stand up
- blurred vision

- 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
- bruising more easily than normal
- unusual bleeding, including bleeding from the stomach or bowel
- difficulty urinating or excess urine production
- tingling or numbness in the hands or feet
- agitation, nervousness, anxiety, confusion
- worsening of depression.

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

- thoughts of suicide or attempting suicide or self-harm
- serious allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- shortness of breath or tightness in the chest
- aggressive behaviour
- tremors, involuntary movement of the muscles
- high fever, agitation, confusion, trembling and abrupt contraction of the muscles (symptoms of a rare condition called Serotonin Syndrome)
- fast, irregular heart beat with feelings of dizziness or difficulty breathing.

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

Other side effects not listed above may also occur in some patients.

An increased risk of bone fractures has been observed in patients taking

medicines like APX-CITALOPRAM.

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

You may not experience any of them.

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## After taking it

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### *Storage*

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

**Keep APX-CITALOPRAM 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.

**Do not store APX-CITALOPRAM or any other medicine in the bathroom or near a sink.**

**Do not leave APX-CITALOPRAM in the car or on window sills.**

Heat and dampness can destroy some medicines.

### *Disposal*

**If your doctor tells you to stop taking APX-CITALOPRAM, 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*

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.

### *Ingredients*

#### **Active ingredient:**

Each tablet contains 20 mg of citalopram (as citalopram hydrobromide).

**Inactive ingredients:****20mg**

- lactose
- cellulose-microcrystalline
- starch-maize
- povidone
- crospovidone
- magnesium stearate
- Opadry White complete film coating system Y-1-7000.

The tablets are gluten free.

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**Sponsor**

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Arrow Pharma Pty Ltd  
15-17 Chapel Street  
Cremorne VIC 3121

20mg

Blister Pack AUST R TBC

Bottle AUST R TBC

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