

APO-Citalopram Tablets

Contains the active ingredient citalopram (as citalopram hydrobromide)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about citalopram. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,

- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Citalopram. It contains the active ingredient citalopram (as citalopram hydrobromide).

It is used to treat depression.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Citalopram belongs to a group of antidepressant medicines called Selective Serotonin Reuptake Inhibitors (SSRIs).

Citalopram and other SSRIs are thought to help by increasing the amount of serotonin in your brain.

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.

There is no evidence that this medicine is addictive.

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

Use in children

Do not give this medicine to a child or adolescent.

The benefit and safety of citalopram use in children and adolescents below 18 years of age has not been proven.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are taking the following other medicines:**
 - **Pimozide (used to treat disorders which affect the way you think, feel or act)**
 - **Monoamine Oxidase Inhibitors (MAOIs), used to treat depression (phenelzine, tranylcypromine, moclobemide), Parkinson's Disease (selegiline) or infections (linezolid).**

Do not take citalopram until 14 days after stopping most MAOIs. The exception is the MAOI, moclobemide, where you may take citalopram one whole day after finishing taking moclobemide.

Taking citalopram with MAOIs may cause a serious reaction with signs such as a sudden increase in body temperature, very high blood pressure, rigid muscles, nausea/vomiting and/or fits (convulsions). Your doctor will know when it is safe to start citalopram after the MAOI has been stopped.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have a condition called Congenital Long QT Syndrome, where your heart beats unusually, and you may feel short of breath, dizzy or faint. Your doctor will tell you if you have this.**
- **You have had an allergic reaction to citalopram or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include 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; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives, lactose or dyes. These tablets contain lactose.
2. You have or have had any medical conditions, especially the following:
 - mania, hypomania, bipolar disorder or any other conditions which affect the way you think, feel or act
 - epilepsy or convulsions, fits or seizures (you should avoid taking citalopram if your epilepsy is not properly controlled; if it is properly controlled your doctor will wish to watch you carefully if you take citalopram)
 - heart problems

- liver problems
- kidney problems
- problems with blood clotting or abnormal bleeding
- thoughts or actions relating to self-harm or suicide
- diabetes
- lactose or galactose intolerance, Lapp lactase insufficiency, glucose or galactose malabsorption

(These tablets contain lactose)

- a decreased level of sodium or potassium in your blood, which may be due to certain medicines (e.g. certain diuretics [water tablets] and antibiotics), or to certain medical conditions (e.g. kidney problems, dehydration, excess sweating or vomiting or diarrhoea). Your doctor will test you for this before you start taking citalopram.
- restlessness and/or a need to move often (akathisia).

3. You are currently pregnant or you plan to become pregnant. There have been reports that babies exposed to certain antidepressants during the third trimester of pregnancy may develop complications after birth.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breast-feeding or you plan to breast-feed. It is not recommended that you breast-feed while

taking this medicine because citalopram passes into breast milk and may affect your baby.

Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.

5. You are receiving electroconvulsive treatment (ECT).
6. You are planning to have, or have very recently had, surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

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

Therefore some medicines must not be taken with citalopram. These include:

- monoamine oxidase inhibitors, such as moclobemide, phenelzine, tranylcypromine, selegiline and linezolid
- pimozide

(see also "When you must not take it" in this leaflet).

Some other medicines may interact with citalopram. These include:

- tryptophan, contained in some multivitamin and herbal preparations
- tramadol, a strong pain killer
- sumatriptan and similar medicines used to treat migraines and cluster headaches
- St John's Wort (*Hypericum perforatum*), a herbal remedy
- other medicines used to treat depression
- lithium, a medicine used to treat mood swings and some types of depression
- any other medicines used to treat anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder.
- antipsychotics, medicines used to treat psychoses, schizophrenia and other conditions which affect the way you think, feel or act (e.g. olanzapine, risperidone)
- prochlorperazine, used to prevent or treat severe nausea and vomiting
- antiarrhythmics, medicines used to treat an irregular heart beat e.g. dipyridamole
- medicines known to prolong bleeding e.g. aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) and anti-coagulants (such as warfarin and ticlopidine), which can thin the blood

- beta-blockers such as metoprolol, used to treat high blood pressure and other heart problems
- ketoconazole and itraconazole, medicines used to treat fungal infections
- macrolide antibiotics, such as erythromycin and clarithromycin
- certain other antibiotics which may lower your potassium or magnesium levels (e.g. penicillin)
- carbamazepine and other medicines used to control epilepsy (fits).
- cimetidine and medicines called proton pump inhibitors (e.g. omeprazole) used to treat reflux and stomach ulcers
- certain diuretics (water tablets)

If you are taking any of these you may need a different dose or you may need to take different medicines.

If you take medicines which affect the heart rhythm whilst taking citalopram then your doctor will do regular tests on your heart (ECG). Citalopram may also cause changes to your heart rhythm.

Other medicines not listed above may also interact with citalopram.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual starting dose for adults is 20 mg per day. Your doctor may increase your dose slowly in stages of 10 mg depending on how you respond to this medicine. The maximum dose is 40 mg a day.

Elderly people have a starting dose of 10 mg per day, which may be increased slowly to a maximum dose of 20 mg. a day.

People who take cimetidine or other medicines which affect the blood levels of citalopram (called CYP 2C19 inhibitors), or people who have liver problems should not take more than 20 mg of citalopram per day.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets whole, with a full glass of water. Do not chew them.

When to take it

Take it as a single dose, either in the morning or in the evening, at about the same time each day.

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

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you, even if it takes some time before you feel any improvement in your condition.

Make sure you have enough to last over weekends and holidays.

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 this medicine.

Your doctor will check your progress at regular intervals.

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

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

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

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.

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.

Stopping Treatment

Do not stop taking this medicine even if you begin to feel better.

Your doctor may decide that you should continue to take it for some time, even when you have overcome your problem. For best effect, this medicine must be taken regularly.

Do not stop taking your medicine suddenly.

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.

Your doctor will tell you how to reduce the dosage so that you help avoid getting any unwanted effects.

If you forget to take it

If you are less than 12 hours late in taking your dose, take the missed dose as soon as you remember and then go back to taking your dose as you normally would.

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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much citalopram you may get symptoms of 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 or sleepiness. Convulsions, coma, and rarely, temporary paralysis or weakness of muscles may occur.

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

While you are taking this medicine

Things you must do

Persons taking citalopram may be more likely to think about killing themselves or actually trying to do so, especially when 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 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.

If you or someone you know or care for is showing any of the following warning signs of suicide-related behaviour while taking this medicine, contact your doctor 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
- worsening of depression.

Follow your doctor's instructions. 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 certain 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 also occur during the first weeks of treatment.

Contact your doctor immediately if you suddenly experience an episode of mania.

Some people with manic depression (bipolar disorder) may enter a manic phase. Symptoms of mania include lots of rapidly changing thoughts or ideas, exaggerated gaiety, being much more physically active and much more restless.

Sometimes you may not know that you are manic, so it may be helpful to have a friend or relative watch over you for any possible signs of change in your behaviour.

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

Tell your doctor immediately if you become pregnant.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking citalopram.

Make sure your midwife and/or doctor know you are taking citalopram. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like citalopram 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 midwife and/or doctor immediately.

Low Potassium or Sodium

Some people (especially older people or those taking diuretics/ water tablets or people who are dehydrated, have diarrhoea or vomiting or take certain antibiotics) may experience a lack of sodium or potassium in the blood when taking this medicine. Tell your doctor if you get a headache or start to feel dizzy, confused, forgetful, weak or fatigued, unsteady or unable to concentrate or if you get muscle weakness or spasms or abnormal heart beats or have problems breathing.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. If you are taking certain other medicines or have heart problems your doctor will monitor you closely.

Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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 this medicine is 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, thoughts of suicide, bursts of unusual energy, anger or aggression, or if you become particularly agitated or restless.

Tell your doctor immediately if your heart beats unusually, and/or you feel short of breath, dizzy or faint.

Make sure you have enough tablets to last over weekends and holidays.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. Your doctor will tell you how to gradually reduce the dose of your medicine. This is

usually done slowly, over 1 to 2 weeks, before stopping completely.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

Avoid alcohol while you are taking this medicine.

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

You should be aware that people over 50 years of age who take antidepressants have an increased risk of having a bone fracture.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking citalopram or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

This list includes the more common side effects. Mostly, these are mild:

- feeling tired and weak (fatigued), hot flushes, fever, feeling unwell, shaking or tremors, migraine, headache, dizziness or giddiness
- muscle, back, bone, nerve or joint pain, stiffness, weakness or cramps, decrease or loss of touch or other senses
- increased or decreased sensitivity to outside stimuli
- feeling or being sick, reflux, diarrhoea or loose bowel motions, constipation, indigestion, stomach pain or discomfort, wind
- increased saliva or dry mouth, taste disturbance
- feeling thirsty
- burping, hiccups, problems swallowing, sore mouth, tongue or throat, haemorrhoids (piles)
- sleepiness, drowsiness, sleeping difficulties, strange dreams
- sexual problems, painful erection

- frightening or unusual dreams, yawning, teeth grinding or clenching, increased or decreased appetite, impaired concentration
- excessive and/or abnormal movements
- increased muscle tension, muscle twitching
- problems with eyes or eyesight
- feeling faint or dizzy when you stand up due to low blood pressure
- unable to tolerate alcohol
- menstrual irregularities, breast pain, unusual vaginal bleeding
- loss of bladder control
- unusual hair loss or thinning
- tingling or numbness of the hands or feet
- drooping eyelid
- breast enlargement or the unusual secretion of breast milk in men or women
- increased sensitivity of the skin to sun
- mild rash, or itching or prickling of the skin
- acne, eczema, dermatitis, dry skin, psoriasis or other skin problem

- ringing or other persistent noise in the ears
- increased or decreased sweating
- bruises or skin discolouration
- weight decrease or weight increase
- flu-like symptoms, runny or blocked nose, sneezing, facial pressure or pain, coughing or sore throat
- a sense of indifference to everything.

Some of these side effects 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.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- nervousness, confusion, problems with concentration, loss of memory
- feeling restless or unable to sit still
- stomach pain with nausea and vomiting of blood, or blood in the bowel movements
- anxiety, agitation, aggression, worsening of depression
- general swelling or swollen hands, ankles, feet or face or eye area due to fluid build-up

- blurred vision
- problems speaking
- feelings of not being part of your body, or in a daze
- feeling sick or unwell with weak muscles or feeling confused (these symptoms may be signs of a rare condition as a result of low levels of sodium in the blood, which may be caused by antidepressants, especially in elderly female patients)
- feeling fatigued with muscle weakness or spasms or abnormal heart beats or problems breathing. This may be due to low potassium levels in your blood.
- increased tendency to develop bruises or broken bones
- passing more or less urine than normal, or problems when urinating
- agitation, anxiety, feeling tense and restless, tired, drowsy, lack of energy, irritable, problems sleeping, headache, nausea and tingling or numbness of the hands and feet after stopping citalopram.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- convulsions (fits or seizures)

- coma (unconsciousness)
- a collection of symptoms including weight gain (despite loss of appetite), feeling and being sick, muscle weakness and irritability
- severe rash, with blisters and/ or excessive peeling of skin
- a sudden increase in body temperature, very high blood pressure, rigid muscles, nausea/vomiting and/or fits (convulsions). These symptoms may be signs of a rare condition called Serotonin Syndrome.
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- fast, slow or irregular heart beat, high blood pressure
- palpitations, fainting or chest pain
- abnormal bleeding
- kidney pain, difficulty in passing urine or blood in the urine
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- fever, sore throat, swollen glands, mouth ulcers, unusual bleeding or bruising under the skin

- mood of excitement, over-activity and uninhibited behaviour or aggression
- hearing, seeing or feeling things that are not there (hallucinations)
- thoughts of suicide or attempting suicide or self-harm
- sudden, severe breathing problems
- feeling paranoid, panicky, or "high" or having mood swings or feeling more depressed or in a trance
- tremors, movement disorders such as involuntary movements of the muscles or being uncoordinated
- jaundice (yellowing of the skin and/or eyes) , with or without other signs of hepatitis or liver problems (loss of appetite, tiredness, feeling or being sick, dark urine, stomach pain or swelling, confusion, unconsciousness).
- sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech

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

Allergic reactions

If you think you are having an allergic reaction to citalopram, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Citalopram look like

APO-Citalopram 20 mg Tablets

White to off-white, oval, biconvex, film-coated tablets, with BL embossed on one side and '20' on the other.

APO-Citalopram 40 mg Tablets

White to off-white, oval, biconvex, film coated tablets with '40' embossed on one and 'BL' embossed on the other side.

Bottle of 28 tablets

Blister Pack of 28 tablets

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 20 mg or 40 mg of citalopram (as citalopram hydrobromide) as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- maize starch
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- hypromellose
- titanium dioxide
- purified talc
- macrogol 400
- purified water

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Citalopram 20 mg tablets

Blister pack of 28 tablets:

AUST R 226578

Bottles of 28 tablets:

AUST R 233166

APO-Citalopram 40 mg tablets

Blister pack of 28 tablets:

AUST R 226579

Bottles of 28 tablets:

AUST R 233165

Sponsor

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