

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Citalopram Sandoz.

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 this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT CITALOPRAM SANDOZ IS USED FOR

This medicine is used for the treatment of depression.

It contains the active ingredient citalopram hydrobromide. Citalopram hydrobromide 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.

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 sexual drive, lack of energy and feeling guilty over nothing.

Citalopram Sandoz 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 it for another reason.

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

Citalopram Sandoz is not addictive.

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

Tell your doctor if you get any side effects after stopping Citalopram Sandoz.

BEFORE YOU TAKE CITALOPRAM SANDOZ

When you must not take it

Do not take Citalopram Sandoz if you have a condition called 'congenital long QT syndrome'. At high doses, Citalopram Sandoz 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 Citalopram Sandoz.

Do not take this medicine if you have an allergy to:

- citalopram hydrobromide, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines, such as medicines of the same class, SSRIs, e.g. sertraline.

Some of the 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
- rash, itching or hives on the skin.

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

- pimozide, a medicine used to treat mental disorders
- linezolid, a medicine used to treat bacterial infections
- monoamine oxidase inhibitors (MAOIs), which are also used for the treatment of depression.

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

Taking Citalopram Sandoz with MAOIs may cause a serious reaction with a sudden increase in temperature, extremely high blood pressure and severe convulsions. Your doctor will know when it is safe to start Citalopram Sandoz after the MAOI has been stopped.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- bleeding disorder
- diabetes
- heart disease
- kidney disease
- liver disease
- bipolar disorder (manic depression)
- a history of seizures or fits
- restlessness and/or a need to move often.

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

Your doctor can discuss with you the risks and benefits involved.

If you take this medicine during the last three months of your pregnancy, the general condition of your newborn baby might be affected.

It is not recommended that you breastfeed while taking Citalopram Sandoz as it is excreted in breast milk.

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

- congenital long QT syndrome or other heart conditions. Your doctor may occasionally need to check your heart beat and rhythm with an ECG test
- illnesses which require you to have regular blood 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.

Tell your doctor if you are receiving electroconvulsive therapy.

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

Citalopram Sandoz tablets contain lactose.

Do not give this medicine to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

Citalopram Sandoz can be given to elderly patients over 65 years of age with a reduced dose. The effects of Citalopram Sandoz in elderly patients are similar to that in other patients.

If you have not told your doctor about any of the above, tell him/her before you start taking Citalopram Sandoz.

Taking other medicines

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

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

- ketoconazole and itraconazole, medicines used to treat fungal infections
- macrolide antibiotics, e.g. erythromycin and clarithromycin, medicines used to treat infections
- medicines used to treat reflux and ulcers e.g. cimetidine and omeprazole
- medicines known to prolong bleeding, e.g. aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac
- warfarin, a medicine used to prevent blood clots
- sumatriptan, a medicine used to treat migraines
- tramadol, a medicine used to relieve pain
- carbamazepine, a medicine used to treat convulsions
- some heart medications, such as beta-blockers (e.g. metoprolol) or antiarrhythmics
- selegiline, a medicine used in Parkinson's disease
- tryptophan, an amino-acid contained in some multivitamin and mineral preparations

- lithium, a medicine used to treat mood swings and some types of depression
- antipsychotics, a class of medicines used to treat certain mental and emotional conditions
- tricyclic antidepressants, e.g. imipramine, desipramine
- St John's Wort (*Hypericum perforatum*), a herbal remedy
- any other medicines for depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder.

These medicines may be affected by Citalopram Sandoz 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.

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 Citalopram Sandoz. If it is necessary for you to be on these medicines at the same time as Citalopram Sandoz, your doctor may perform an ECG test to check your heart rate and rhythm.

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

HOW TO TAKE CITALOPRAM SANDOZ

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

They may differ from the information contained in this leaflet.

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

How much to take

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

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

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 Citalopram Sandoz 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 they give you.

If you take the wrong dose, Citalopram Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

If you need to break Citalopram Sandoz tablets into two halves, place on a flat surface

and press down on the scored side with the thumb or forefinger.

When to take Citalopram Sandoz

Take Citalopram Sandoz as a single dose either in the morning or in the evening.

Take your medicine 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 remember when to take it.

Take Citalopram Sandoz with or without food.

How long to take Citalopram Sandoz

Continue taking your medicine 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 Citalopram Sandoz. 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 Citalopram Sandoz 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 heart beat.

Your doctor will tell you how to reduce the dosage so that you do not get unwanted effects.

If you forget to take it

If you miss a dose and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally.

Otherwise, if it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Citalopram Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea (feeling sick), vomiting, dizziness, fast or slow heart beat or change in heart rhythm, decreased or increased blood pressure, tremor (shaking), agitation, dilated pupils of the eyes, drowsiness and sleepiness. Convulsions or coma may occur. A condition called serotonin syndrome may occur with high fever, agitation confusion, trembling and abrupt contractions of muscles.

WHILE YOU ARE TAKING CITALOPRAM SANDOZ

Things you must do

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

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

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor immediately if you have thoughts about killing yourself or other mental or mood changes, or if you are close to or care for someone using Citalopram Sandoz who talks about or shows signs of killing him or herself.

Persons taking Citalopram Sandoz may be more likely to think about killing themselves or actually trying to do so, especially when Citalopram Sandoz 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 until the full antidepressant effect of the medicine become 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 demonstrates any of the following warning signs of suicide-related behaviour while taking Citalopram Sandoz, tell your doctor immediately, or go to the nearest hospital for treatment; patients and care givers should pay attention to these warning signs:

- 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 you doctor, even if you experience increased anxiety at the beginning of the treatment.

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

Tell your doctor immediately if you experience symptoms such as restlessness or difficulty in sitting or standing still.

These symptoms can occur during the first week of treatment.

Contact your doctor as soon as possible if you 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.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Citalopram Sandoz to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

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

Do not let yourself run out of medicines over the weekend or on holidays.

Things to be careful of

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

This medicine 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.

Avoid alcohol while you are taking this medicine.

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

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- rash, 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
- insomnia
- a sense of indifference to everything
- disturbance in attention
- lack of energy
- sexual disturbances (decreased sexual drive, problems with orgasm; problems with ejaculation or erection)
- for females, problems with menstrual periods
- restlessness or difficulty keeping still.

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

- chest pain
- fast heart rate (palpitations) or decrease in heart rate
- 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 muscle or feeling confused) which may be caused by SSRI antidepressants, especially in elderly patients
- increased tendency to develop bruises
- unusual bleeding, including bleeding from stomach or bowel
- 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.

The above list includes serious side effects of Citalopram Sandoz that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 heart beat with feelings of dizziness or difficulty breathing.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation.

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

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

Other side effects not listed above may occur in some people. An increased risk of bone fractures has been observed in patients taking medicines like Citalopram Sandoz.

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

You may not experience any of them.

AFTER TAKING CITALOPRAM SANDOZ

Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

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

Do not store Citalopram Sandoz 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 it 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Citalopram Sandoz comes in 2 types of tablets:

Citalopram Sandoz 20mg - white, oval, biconvex film-coated tablets with a score notch on one side, and embossed C 20.

Available in bottles and blister packs of 28 tablets.

Citalopram Sandoz 40mg - white, oval, biconvex film-coated tablets with a score notch on one side, and embossed C 40.

Available in blister packs of 28 tablets.

All strengths and presentations may not be marketed.

Ingredients

Active ingredients:

- Citalopram Sandoz 20mg tablet - 20mg citalopram as citalopram hydrobromide
- Citalopram Sandoz 40mg tablet - 40mg citalopram as citalopram hydrobromide.

Inactive ingredient:

- maize starch
- lactose monohydrate
- copovidone
- glycerol
- microcrystalline cellulose
- magnesium stearate
- sodium starch glycollate

- hypromellose
- macrogol 6000
- titanium dioxide
- purified talc.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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20mg tablets: AUST R 101691 (blisters)

20mg tablets: AUST R 101690 (bottle)

40mg tablets: AUST R 107061 (blisters)