

Citalopram AMNEAL

Film-Coated Tablets

Contains the active ingredients citalopram hydrobromide

Consumer Medicine Information

What is in this leaflet

This leaflet contains answers to some common questions about Citalopram AMNEAL.

It does not contain all the information that is known about Citalopram AMNEAL. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.

Keep this leaflet with the medicine.

You may need to read it again.

What Citalopram AMNEAL is used for

Citalopram AMNEAL is used to treat depression. It 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 sex drive, lack of energy and feeling guilty over nothing.

Citalopram AMNEAL 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.

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

Citalopram AMNEAL 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 AMNEAL.

Before you take it

When you must not take it

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

Do not take Citalopram AMNEAL if you are allergic to it or any of the ingredients listed at the end of this leaflet.

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.

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

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

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

Taking Citalopram AMNEAL 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 Citalopram AMNEAL after the MAOI has been stopped.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

1. you have allergies to any other substances such as foods, preservatives or dyes.

2. you are pregnant or intend to become pregnant.

Do not take Citalopram AMNEAL if you are pregnant unless you and your doctor have discussed 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.

3. you are breast-feeding or planning to breast-feed.

Do not take Citalopram AMNEAL 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 Citalopram AMNEAL as it is excreted in breast milk.

4. 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.

5. you are receiving electroconvulsive therapy.

If you are lactose intolerant, contact your doctor before taking Citalopram AMNEAL.

Citalopram AMNEAL tablets contain lactose.

Do not give Citalopram AMNEAL to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Citalopram AMNEAL can be given to elderly patients over 65 years of age with a reduced dose.

The effects of Citalopram AMNEAL in elderly patients are similar to that in other patients.

If you have not told your doctor about any of the above, tell them before you use Citalopram AMNEAL.

Taking other medicines

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

Some medicines and Citalopram AMNEAL 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 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
- sumatriptan, used to treat migraines
- tramadol, 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 to treat Parkinson's disease
- tryptophan, an amino-acid

- lithium, 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 AMNEAL, 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 Citalopram AMNEAL. If it is necessary for you to be on these medicines at the same time as Citalopram AMNEAL, 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 Citalopram AMNEAL.

How to take it

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.

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 AMNEAL 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 AMNEAL may not work as well and your condition may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

When to take it

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

Take Citalopram AMNEAL with or without food.

How long to take it

Continue to take Citalopram AMNEAL 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 AMNEAL. 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 AMNEAL 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 beats.

When you have completed your course of treatment, the dose of Citalopram AMNEAL 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 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 you have missed.

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (Tel: 13 11 26 for Australia), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Citalopram AMNEAL.

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 it

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 AMNEAL.

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

If you become pregnant while taking Citalopram AMNEAL, tell your doctor immediately.

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

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 weeks 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.

Things you must not do

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

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

Do not stop taking Citalopram AMNEAL, 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 Citalopram AMNEAL may cause unwanted discontinuation symptoms such as dizziness, headache and nausea. Your doctor will tell you when and how Citalopram AMNEAL 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.

Things to be careful of

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

Avoid alcohol while you are taking this medicine.

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

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

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

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

The side effects of Citalopram AMNEAL are, in general, mild and disappear after a short period of time.

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

- 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

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

- 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 feeling confused) which may be caused by SSRI antidepressants, especially in elderly patients
- increased tendency to develop bruises
- unusual bleeding, including bleeding from the 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.

These may be serious side effects of Citalopram AMNEAL. You may need urgent medical attention.

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

- 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

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

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

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 AMNEAL.

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

You may not experience any of them.

After taking it

Storage

Keep Citalopram AMNEAL tablets in the blister and bottle until it is time to take them.

If you take the tablets out of the box, blister or bottle they may not keep well.

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

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp 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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Citalopram AMNEAL 10mg tablets are white to off-white, round, plain, film-coated tablets.

Citalopram AMNEAL 20mg tablets are white to off-white, oval, biconvex, film-coated tablets, with BL embossed on one side & '20' on the other.

Citalopram AMNEAL 40mg tablets are white to off-white, oval, biconvex, film-coated tablets, with BL embossed on one side & '40' on the other.

Citalopram AMNEAL tablets are available in blister packs of 28 tablets.

Ingredients

Active ingredient(s):

- Citalopram AMNEAL tablets – contain 10, 20 or 40 mg of citalopram (as hydrobromide) per tablet

Inactive ingredients:

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

- purified talc

Citalopram AMNEAL does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3103

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2016

ARTG number:

Citalopram AMNEAL tablets

10 mg AUST R 158879(blister).

20 mg AUST R 158881(blister).

40 mg AUST R 158883(blister).