

## Citalopram AN tablets

Citalopram hydrobromide

### Consumer Medicine Information

#### What is in this leaflet

Please read this leaflet carefully before you start CITALOPRAM AN.

This leaflet answers some common questions about CITALOPRAM AN. 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 CITALOPRAM AN against the benefits it is expected to 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 AN is used for

CITALOPRAM AN 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 AN 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 CITALOPRAM AN has been prescribed for you.**

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

CITALOPRAM AN 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 AUROCITALOPRAM AN.**

#### Before You Take CITALOPRAM AN

##### *When you must not take it*

**Do not take CITALOPRAM AN if you have a condition called 'congenital long QT syndrome. At high doses, CITALOPRAM AN 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 AN.**

**Do not take CITALOPRAM AN 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 AN at the same time as the following other medicines:**

- pimozide, a medicine used to treat mental disorders
  - monoamine oxidase inhibitors
  - (MAOIs), which are also used for the treatment of depression.
- Do not take CITALOPRAM AN when you are taking a MAOI or when you have been taking a MAOI within the last 14 days.

Taking CITALOPRAM AN 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 AN after the MAOI has been stopped.

**Do not take CITALOPRAM AN 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*

**You must 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 AN 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 new born baby might be affected.
3. **you are breast-feeding or planning to breast-feed.**  
Do not take CITALOPRAM AN if you are breastfeeding unless you and your doctor have discussed the risks and benefits involved. It is not recommended that you breastfeed while taking CITALOPRAM AN 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
  - illness 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 treatment**
  - **If you are lactose intolerant, contact your doctor before taking**

#### CITALOPRAM AN.

CITALOPRAM AN tablets contain lactose.

- **Do not give CITALOPRAM AN to a child or adolescent.**  
There is no experience with its use in children or adolescents under 18 years old.
- **CITALOPRAM AN can be given to elderly patients over 65 years of age with a reduced dose.**  
The effects of CITALOPRAM AN 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 AN.**

#### *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 AN 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 premenstrual dysphoric disorder.

These medicines may be affected by CITALOPRAM AN, 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, antihistamines) should be avoided while taking**

**CITALOPRAM AN. If it is necessary for you to be on these medicines at the same time as CITALOPRAM AN, 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 AN.

---

## How to take CITALOPRAM AN

---

### *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 per day.

The recommended starting dose in elderly patients is 10 mg per day but may be increased to a maximum of 20 mg 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 10 mg per day. The dose can be increased to a maximum of 20 mg per day.

**Your doctor may have prescribed a different dose. If you have been prescribed or are currently taking doses of CITALOPRAM AN greater than 40 mg, 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 AN 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 your tablet at about the same time each day, either morning or evening. Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it.

CITALOPRAM AN can be taken with or without food.

### *How long to take it*

**Continue to take CITALOPRAM AN 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 AN. 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 the medicine is stopped suddenly you may experience mild, but usually temporary, symptoms such as dizziness, feelings like pins and needles, sleep disturbances (vivid dreams, inability to sleep), feeling anxious or agitated, headaches, feeling sick (nausea), vomiting, sweating, tremor (shaking), feeling confused, feeling emotional or irritable, diarrhoea, visual disturbances, or fast or irregular heartbeats.

When you have completed your course of treatment, the dose of CITALOPRAM AN 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 Poisons Information Centre - the telephone number in Australia is 131 126 or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much CITALOPRAM AN.**

**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 AN

---

### *Things you must do*

**If you are about to start any new medicine, tell your doctor or pharmacist that you are taking CITALOPRAM AN.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking CITALOPRAM AN.**

**If you become pregnant while taking CITALOPRAM AN, tell your doctor immediately.**

**Persons taking CITALOPRAM AN may be more likely to think about killing themselves or actually trying to do so, especially when CITALOPRAM AN 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 AN 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 – 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 AN. 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 also 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 AN to treat any other complaints unless your doctor tells you to.**

**Do not stop taking CITALOPRAM AN, 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 AN may cause unwanted discontinuation symptoms such as dizziness, headache and nausea.

Your doctor will tell you when and how CITALOPRAM AN 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 AN affect 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 AN.

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

The side effects of CITALOPRAM AN 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 AN. 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 medicine like CITALOPRAM AN.

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

You may not experience any of them.

---

### After taking CITALOPRAM AN

---

#### Storage

##### Keep your CITALOPRAM AN tablets in the pack until it is time to take them.

If you take your tablets out of the pack they will not keep as well.

##### Keep CITALOPRAM AN tablets in a cool dry place where the temperature stays below 25°C.

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

Do not leave your medicines in the car. Heat and dampness can destroy some medicines.

##### Keep CITALOPRAM AN 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 CITALOPRAM AN 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 AN tablets comes in 10 mg, 20 mg & 40 mg.

CITALOPRAM AN 10 mg comes in pack sizes of 28 (blister pack) & in pack sizes of 30 (HDPE bottle pack)

CITALOPRAM AN 10 mg (Blister pack: AUST R 171334 & Bottle: AUST R 171335) are white coloured, biconvex, round shaped film coated tablets, debossed with 'A' on one side and '05' on the other side.

CITALOPRAM AN 20 mg (Blister pack: AUST R 171336 & Bottle: AUST R 171337) are white coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and with a score line in between '0' and '6' on the other side.

CITALOPRAM AN 40 mg (Blister pack: AUST R 171338 & Bottle: AUST R 171339) are white coloured, biconvex, round shaped film coated tablets, debossed with 'A' on one side and with score line in between '0' and '7' on the other side.

#### Ingredients

##### Active Ingredient:

- CITALOPRAM AN 10 mg contains 10 mg citalopram (as hydrobromide) per tablet
- CITALOPRAM AN 20 mg contains 20 mg citalopram (as hydrobromide) per tablet
- CITALOPRAM AN 40 mg contains 40 mg citalopram (as hydrobromide) per tablet

##### Other Ingredients:

- Lactose monohydrate
- Maize starch
- Copovidone
- Croscarmellose sodium
- Cellulose microcrystalline
- Magnesium stearate
- Hypromellose
- Macrogol 400
- Titanium dioxide

CITALOPRAM AN does not contain gluten, sucrose, tartrazine or any other azo dyes.

#### Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd,  
12 River St  
South Yarra  
VIC – 3141  
Australia

#### Date of Preparation

August 2016