

Consumer Medicine Information

ARROW - CITALOPRAM

Citalopram (as hydrobromide) 20 mg Tablets

What is in this leaflet

This leaflet answers some common questions about ARROW - CITALOPRAM.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ARROW - CITALOPRAM against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What ARROW - CITALOPRAM is used for

ARROW - CITALOPRAM is used to treat depression and helps prevent potential recurrence of the symptoms of depression.

It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs 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 chemical imbalance in some 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 over-eating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

ARROW - CITALOPRAM corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor may have prescribed ARROW - CITALOPRAM for another reason.
Ask your doctor if you have any questions about why ARROW - CITALOPRAM has been prescribed for you.

ARROW - CITALOPRAM is not recommended for use in children and adolescents under 18 years of age, as safety and efficacy have not been established in this population.

ARROW - CITALOPRAM can be given to elderly patients with a reduced dose. The effects of ARROW - CITALOPRAM in elderly patients are similar to that in other patients.

There is no evidence that ARROW - CITALOPRAM is addictive.

ARROW - CITALOPRAM is available only with a doctor's prescription.

Before you take ARROW - CITALOPRAM

When you must not take it

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

Some of the symptoms of an allergic reaction may include skin rash, itching or 'hives'; swelling of the face, lips or tongue that may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take ARROW - CITALOPRAM if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days.

Taking ARROW - CITALOPRAM with a MAOI may cause serious reactions including shaking (tremor), shivering, muscle stiffness, sudden increase in body temperature, extremely high blood pressure and severe convulsion. Examples of MAOIs are phenelzine (Nardil®), meclobemide (Aurorix®) and tranylcypromine (Parnate®). There may be others, so please check with your doctor or pharmacist.

Do not take ARROW - CITALOPRAM if you are taking pimozide, a medicine used to treat mental disorder.

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

It may not work as well if you do.

Do not take ARROW - CITALOPRAM if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your pharmacist or doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of taking ARROW - CITALOPRAM during pregnancy. The general condition of your newborn baby might be affected by the medicine.

If you take an antidepressant that belongs to the SSRI group of medicine during the last three months of your pregnancy and until your baby is born, the following effects may be seen in your newborn: trouble with breathing, blueish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. If your newborn baby has any of these symptoms, please contact your doctor immediately.

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

Citalopram passes into breast milk. Your doctor will discuss the risks and benefits of taking ARROW - CITALOPRAM when breastfeeding.

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

- bleeding disorder
- epilepsy, seizures or fits
- diabetes
- liver disease
- kidney disease
- heart disease
- mania and/or bipolar disorders (manic/depressive illness)
- a decreased level of sodium in your blood
- restlessness and/or a need to move often (akathisia).

Tell your doctor if you are receiving the electroconvulsive therapy (e.g. for mental disorders).

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

Taking other medicines

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

Some medicines may be affected by ARROW - CITALOPRAM, or may affect how well it works. These include:

- monoamine oxidase inhibitor (MAOI; either currently taking or have taken it in the last 14 days)
- pimozone
- ketoconazole and itraconazole, medicines used to treat fungal infections
- macrolide antibiotics, e.g. erythromycin and clarithromycin
- cimetidine and omeprazole, medicines used to treat reflux and ulcers
- medicines known to prolong bleeding, e.g. warfarin, aspirin or non-steroidal anti-inflammatory drugs (NSAIDs)
- serotonergic drugs, e.g. sumatriptan (Imigran[®], MyGran[®]) for migraine, tramadol (Tramal[®]) for pain, tryptophan (amino acid) in vitamin and mineral supplements
- tricyclic antidepressants, e.g. imipramine, desipramine
- St. John's wort (*Hypericum perforatum*), a herbal remedy
- lithium, used to treat mood swings and some types of depression
- any other medicines for depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder
- antipsychotics, medicines used to treat certain mental and emotional conditions
- some heart medications, such as beta-blockers (e.g. metoprolol) or anti-arrhythmics
- selegiline, a medicine used to treat Parkinson's disease
- carbamazepine, used to treat epilepsy.

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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ARROW - CITALOPRAM.

How to take ARROW - CITALOPRAM

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

How much to take

The dose varies from patient to patient.

Adults: the usual starting dose is 20 mg (one tablet) per day. Your doctor may increase the dose slowly over several weeks, up to 60 mg (three tablets) a day, depending on how you respond to this medicine.

Elderly patients: 20 mg per day, starting with 10 mg daily. Your doctor may increase this dose up to 40 mg (two tablets) a day.

It usually takes 2 to 3 weeks before any response to ARROW - CITALOPRAM is noticeable. Your doctor may adjust the dose every 2 to 3 weeks, depending on how you respond to the medicine and the severity of your depression.

How to take it

Swallow the tablets with a glass of water. The tablet can be taken with or without food.

When to take it

ARROW - CITALOPRAM can be taken either in the morning or evening.

How long to take it

Keep taking ARROW - CITALOPRAM every day, as it takes some time before you feel any improvement in your condition.

Like other drugs of this type, ARROW - CITALOPRAM will not relieve your symptoms straight away. You should start to feel better after a few weeks, depending on your response. The duration of treatment may vary for each individual, but is usually at least 6 months. In some cases, the doctor may decide that a longer treatment is necessary.

Keep taking ARROW - CITALOPRAM for as long as your doctor tells you, even if you begin to feel better.

The underlying illness may persist for a long time. 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, 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, fluttering or pounding heartbeat (palpitations).

When you have completed your course of treatment, it is therefore advised that the dose of ARROW - CITALOPRAM 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 ARROW - CITALOPRAM

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

Otherwise, take the missed dose as soon as you remember (if less than 12 hours to the next dose), and then go back to taking your tablets as you would normally.

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

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

If you take too much ARROW - CITALOPRAM (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766), or go to Accident and Emergency department at your nearest hospital, if you think that you or anyone else may have taken too much ARROW - CITALOPRAM.

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), dizziness, fast heartbeat or change in heart rhythm, decreased or increased blood pressure, tremor (shaking), agitation, dilated pupils of the eyes, drowsiness and 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 ARROW - CITALOPRAM

Things you must do

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

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

If you become pregnant while taking ARROW - CITALOPRAM, tell your doctor.

Follow your doctor's order carefully and make regular visits, so he/she can check on your progress.

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

All mentions of suicide or violence must be taken seriously.

If you or someone you know is demonstrating any of the following warning signs of suicide-related behaviour while taking ARROW - CITALOPRAM, contact your doctor or a mental health professional immediately or 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.

Tell your doctor immediately if you notice any of the following, especially if they are severe, abrupt in onset, or are not usually part of your depressive symptoms:

- anxiety (increased anxiety can occur at the start of therapy but will disappear with continued treatment - do not stop the medicine or change the dose)
- akathisia (restlessness or difficulty in sitting or standing still; can occur in the first few weeks of therapy)
- panic attacks
- insomnia (difficulty sleeping)
- agitation, irritability, hostility (aggressiveness), impulsivity
- hypomania, mania (mood of excitement, over-activity and uninhibited behaviour)

worsening of depression or other symptoms.

Tell your doctor immediately if you experience episodes of mania.

Some patients with bipolar disorder (manic depression) may enter into a manic phase. This is characterised by profuse and rapidly changing thoughts or ideas, exaggerated gaiety and excessive physical activity.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it is not working as it should be and change your treatment unnecessarily.

Sometimes, you may not be aware of the symptoms mentioned above. Therefore, you may find it helpful to ask a friend or relative to help you observe the possible signs of change in your behaviour.

Things you must not do

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

Stopping ARROW - CITALOPRAM suddenly may cause symptoms such as dizziness, anxiety, headache and nausea. Your doctor will tell you when and how ARROW - CITALOPRAM should be discontinued. Your doctor will gradually reduce the amount of ARROW - CITALOPRAM you are taking, usually over a period of one to two weeks, before stopping it completely.

Also, do not let yourself run out of this medicine over the weekend or on holidays.

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

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

Things to be careful of

Be careful of thoughts of suicide or self-harm.

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. under 30 years old and you have not used antidepressive medicines before.

Be careful driving or operating machinery until you know how ARROW - CITALOPRAM affects you.

ARROW - CITALOPRAM may cause fatigue and dizziness in some people, especially at the start of the therapy. 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.

ARROW - CITALOPRAM has not been shown to increase the effects of alcohol. However, 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 ARROW - CITALOPRAM.

ARROW - CITALOPRAM helps most people with depression. However, like all other medicines, it may have unwanted side effects in some people. 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 this list of possible side effects.

You may not experience any of them.

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

The side effects of ARROW - CITALOPRAM 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:

- skin rash or itching
- ringing or other persistent noise in the ears
- aching muscles or joint pain
- flu-like symptoms, e.g. fever, runny or blocked nose, sneezing, facial pressure or pain, coughing or sore throat, muscle or joint pain

- increased sweating
- increased saliva or dry mouth; taste disturbance
- loss of appetite or increased appetite; weight decreased or increased
- diarrhoea, constipation, flatulence, indigestion, stomach pain or discomfort
- dizziness
- sleepiness or drowsiness, fatigue, yawning
- nausea (feeling sick) or vomiting
- migraine, headache
- sense of indifference to everything
- sexual disturbances (decreased sexual drive, problems with orgasm; problems with ejaculation or erection)
- problems with menstrual periods.

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

- chest pain
- fast or slow heartbeat
- dizziness when you stand up due to low blood pressure
- blurred or abnormal vision
- increased tendency to develop bruises
- unusual bleeds, e.g. bleeding from the stomach or bowel that may be seen as black or dark-red faeces
- 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. You may need urgent medical attention.

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

- thoughts of suicide
- serious allergic reaction (symptoms of an allergic reaction may include skin rash or 'hives'; swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing)
- 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 use of citalopram with other antidepressants or serotonergic drugs)
- tremors, movement disorders (involuntary movements of the muscles)
- 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).

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After taking ARROW - CITALOPRAM

Storage

Keep ARROW - CITALOPRAM where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

Do not store ARROW - CITALOPRAM or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking ARROW - CITALOPRAM, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

ARROW - CITALOPRAM is a white, round tablet with a break line on one side and a 'CT20' on the other side. Each blister pack contains 28 tablets.

Ingredients

The active ingredient in ARROW - CITALOPRAM is citalopram (as hydrobromide). Each ARROW - CITALOPRAM tablet contains 20 mg of citalopram.

The tablets also contain:

- mannitol
- microcrystalline cellulose
- silica colloidal anhydrous
- magnesium stearate
- hypromellose
- titanium dioxide (E171)
- macrogol.

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

ARROW - CITALOPRAM is distributed in New Zealand by:

Arrow Pharmaceuticals (NZ) Limited

33a Normanby Road, Mt Eden
Auckland, New Zealand.

Date of preparation

26 September 2007