

CITALOPRAM-RL(TM) TABLETS

citalopram

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Citalopram-RL tablets.

This leaflet answers some common questions about Citalopram-RL tablets. 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 risks and benefits. Your doctor has weighed the expected benefits of you taking Citalopram-RL tablets against the risks this medicine could 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 are Citalopram-RL tablets used for?

Citalopram-RL is used for the treatment of depression.

Citalopram-RL belongs to a group of medicines called antidepressants.

Citalopram-RL works by relieving the symptoms of depressed mood. It acts on certain chemicals in specific areas of the brain.

Your doctor may have prescribed Citalopram-RL tablets for another reason.

Citalopram-RL tablets are not addictive.

Before you take Citalopram-RL tablets

Antidepressants can increase suicidal thoughts and actions in some children and adolescents younger than 18 years of age. But suicidal thoughts and actions can also be caused by depression, a serious medical condition that is commonly treated with antidepressants. Thinking about killing yourself or trying to kill yourself is called suicidality or being suicidal.

Antidepressants are used to treat depression and other illnesses. Depression and other illnesses can lead to suicide. In some children and adolescents, treatment with an antidepressant increases suicidal thinking or actions. It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your doctor, not just the use of antidepressants.

Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present.

(See Use In Children and Adolescents).

Do not take if:

You must not take Citalopram-RL tablets if:

- * you have ever had an allergic reaction to citalopram or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- * you are taking a group of drugs called the monoamine oxidase inhibitors (MAOIs). It is recommended that you do not start taking Citalopram-RL until at least 14 days after you have finished taking any of these MAOIs such as phenelzine (Nardil) and tranylcypromine (Parnate). Similarly Citalopram-RL should not be taken until at least one day after you have finished taking moclobemide (Aurorix).
- * you are taking pimozide (Orap)
- * **the expiry date (EXP) printed on the pack has passed.**
- * **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- * **you are allergic to foods, dyes, preservatives or any other medicines.**
- * **you are pregnant or intend to become pregnant.**

Citalopram-RL is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using Citalopram-RL if you are

pregnant. One of these risks is that newborn babies whose mothers have been taking Citalopram-RL may have several problems including breathing difficulties, seizures and lack of oxygen in their blood.

*** you are breastfeeding or planning to breastfeed.**

Citalopram-RL passes into breastmilk and there is a possibility that the breastfed baby may be affected. For this reason, the use of Citalopram-RL is not recommended in breastfeeding women.

*** you have or have had any medical conditions, especially the following:**

- heart disease, Citalopram-RL may decrease your heart rate
- epilepsy
- liver disease
- kidney disease
- diabetes
- bleeding disorder
- mania and/or bipolar disorder
- lactose intolerance
- galactose intolerance
- Lapp lactase deficiency
- Glucose-galactose malabsorption.

*** you are taking any other medicines, including medicines you buy without a prescription such as:**

- Medicines used to treat reflux and ulcers eg cimetidine and omeprazole.
- Sumatriptan, used to treat migraines.
- Beta blockers, medicines used to treat high blood pressure eg metoprolol.
- Herbal preparations containing St John's Wort.
- Lithium, used to treat some types of mood disorders.
- Tryptophan contained in some multivitamin and mineral preparations.
- Warfarin, used to prevent blood clots.

- Carbamazepine, used to treat epilepsy.
- Tramadol, a medicine used to relieve pain.
- Selegiline, a medicine used in Parkinson's disease.
- Aspirin and non-steroidal anti-inflammatory drugs (NSAIDS) eg ibuprofen, diclofenac.
- Ketoconazole and itraconazole, medicines used to treat fungal infections.
- Tricyclic antidepressants, used to treat depression eg imipramine.
- Other medicines used to treat depression.
- Erythromycin and clarithromycin, used to treat infections.
- Antiarrhythmics, medicines used to treat irregular heart beats.
- Antipsychotics, medicines used to treat mental disorders.

How do I take Citalopram-RL tablets

How much to take

Take Citalopram-RL tablets as directed by your doctor or pharmacist.

How to take it

Citalopram-RL should be taken once a day, in the morning or evening. It can be taken with or without food. Your doctor will tell you how much Citalopram-RL to take. The usual adult dose of Citalopram-RL is between 20mg and 60mg per day (one to three tablets per day). For the elderly, the usual dose of Citalopram-RL is 20mg to 40mg per day (one to two tablets per day).

If you need to break Citalopram-RL tablets into two halves, place on a flat surface and press down on the scored side with the thumb or forefinger.

How long to take it for

Do not stop taking Citalopram-RL tablets, or change the dose without first checking with your doctor.

Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with Citalopram-RL, especially if this is done suddenly, you may experience unwanted symptoms. Never change the dose of your medicine without talking to your doctor first.

You will not usually feel the full benefit of Citalopram-RL straight away. Individuals will vary greatly in their response to Citalopram-RL. Your doctor will check your progress at regular intervals.

Use in children and adolescents

Citalopram-RL is not recommended for use in children and adolescents under 18 years.

Family and caregivers of children and adolescents being treated with antidepressants for major depressive disorder or for any other condition (psychiatric or non-psychiatric) need to monitor them for the emergence of agitation, irritability, unusual changes in behaviour, as well as the emergence of thoughts of suicide, and to report such symptoms immediately to their doctor. It is particularly important that monitoring be undertaken during the initial few months of antidepressant treatment or at times of dose increase or decrease.

If you forget to take it

If you miss a dose and remember in less than 12 hours, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due. Do not take a double dose to make up for the dose you missed.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Citalopram-RL tablets, even if there are no signs of discomfort or poisoning.

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

While you are taking Citalopram-RL tablets

Things you must do

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

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

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Citalopram-RL tablets to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how Citalopram-RL tablets affect you.

It is best to avoid alcohol while you are taking Citalopram-RL.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking

Citalopram-RL tablets, even if the problem is not listed below.

Like other medicines, Citalopram-RL tablets can cause some side effects.

If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

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

- * nausea, dry mouth
- * drowsiness
- * sweating
- * tremor, headache, dizziness
- * visual disturbances
- * agitation, nervousness, anxiety, poor concentration
- * constipation, diarrhoea
- * trouble when urinating
- * fast heart beats
- * weak body
- * restlessness
- * weight decrease and increase

These are the more common side effects of Citalopram-RL. Mostly, these are mild and short lived.

Less frequent side effects may include:

- * rash, itching
- * migraine
- * numbness or tingling
- * unusual taste, loss of appetite, increased saliva
- * decreased sex drive, impotence, ejaculation failure
- * abnormal dreaming
- * a sense of indifference to everything
- * confusion
- * yawning
- * vomiting, difficulty in digestion, stomach pain, excessive amount of air or gas in the stomach or intestine
- * inflammation of the nasal lining
- * passing more urine than normal
- * fatigue
- * for females, problems with periods
- * abnormal bleeding, including

nose bleeds and gastrointestinal bleeding

- * joint pain
- * slow heart beat or fast heart beat.

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.

Rare side effects may include:

- * rash caused by light.
- * convulsions
- * ringing in the ears
- * aggressive behaviour
- * for females, failure to achieve an orgasm
- * euphoria
- * coughing, shortness of breath
- * bodily discomfort
- * bleeding disorders
- * hepatitis.

Tell your doctor immediately if you experience any of the following:

- * suicidal thoughts
- * suicide attempts.

Tell your Doctor immediately or go to the Accident and Emergency Department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

Tell your doctor immediately if you notice any of the following:

- * **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**
- * **Headache, fever, muscle pain, confusion and convulsion. These could be a symptom of Serotonergic Syndrome.**

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Citalopram-RL tablets?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep Citalopram-RL tablets in a cool, dry place where it stays below 25 degrees C.

Do not leave in a car, on a window sill or in the bathroom.

Keep Citalopram-RL tablets in the container supplied until you need to take it.

Return any unused or expired medicine to your pharmacist.

Product description

What Citalopram-RL tablets look like

Citalopram-RL tablets are white, oblong, biconvex, film-coated tablets with a score notch on one side and embossed C 20.

Ingredients

Citalopram-RL tablets contains 20mg citalopram as citalopram hydrochloride.

Citalopram-RL tablets also contains maize starch, lactose, copovidone, glycerol, cellulose- microcrystalline, magnesium stearate, sodium starch glycollate, hypromellose, macrogol 6000, titanium dioxide and talc-purified.

Citalopram-RL tablets contain lactose.

Supplier

Your Citalopram-RL tablets are supplied by:

Real-RL

A Division of

GlaxoSmithKline Australia Pty Ltd

1061 Mountain Highway

Boronia Victoria 3155

AUSTRALIA

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared on 8 January 2008.

The information provided applies only to: Citalopram-RL(TM)
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