

PACKAGE LEAFLET: INFORMATION FOR THE USER

STARCITIN

20mg Film-coated tablets

CITALOPRAM

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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1. WHAT STARCITIN IS AND WHAT IS IT USED FOR

Citalopram is a Selective Serotonin Reuptake Inhibitors (SSRIs) and belongs to a group of medicines called antidepressants. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

STARCITIN Tablets are used for the treatment of depression and when you feel better, to help prevent these symptoms recurring. STARCITIN Tablets is also used for long-term treatment to prevent the occurrence of new episodes of depression or if you have recurrent depression.

STARCITIN Tablets are also used to relieve symptoms if you are suffering from panic attacks.

2. BEFORE YOU TAKE STARCITIN

Do not take STARCITIN Tablets and talk to your doctor:

- if you are allergic (hypersensitive) to citalopram or to any of the other ingredients of STARCITIN Tablets
- if you are also taking a medicine containing pimozide (Antipsychotic).

- if you are taking medicines known as monoamine oxidase inhibitors (MAOIs).
- MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, moclobemide (used for the treatment of depression), selegiline (used in the treatment of Parkinson's disease) and linezolid (an antibiotic). Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine then you will need to wait 2 weeks before you start taking your STARCITIN Tablets. One day must elapse after you have finished taking moclobemide. After stopping STARCITIN Tablets you must allow 1 week before taking any MAOI.
- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm. Also refer to the section "Taking other medicines" below.

Take special care with STARCITIN Tablets

- If you suffer or have suffered from heart problems or have recently had a heart attack
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- If you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.

Please tell your doctor if you are suffering from

- Liver disease.
- Severe kidney disease.
- Diabetes (you may need an adjustment of your antidiabetic therapy).
- Epilepsy or a history of seizures or fits.
- A bleeding disorder or have ever suffered from bleeding in the stomach or intestine.
- Eye problems, such as certain types of glaucoma.
- Mania or panic disorder.
- Low blood levels of sodium.
- ECT (electroconvulsive therapy).

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Special information relating to your disease

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of Citalopram treatment it may take several weeks before you experience any improvement. In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during continued treatment. Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age

STARCITIN Tablets should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 years have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe citalopram for patients under 18 years because he/she decides that this is in their best interests. If your doctor has prescribed STARCITIN Tablets for a patient under 18 years and if you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 years are taking STARCITIN Tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram in this age group have not yet been demonstrated.

Taking other medicines

Medicines may affect the action of other medicines and this can sometimes cause serious adverse reactions. Please tell your doctor if you are taking or have taken any other medicines (including those purchased without prescription) during the last 14 days. This includes other medicines for depression (see Do not take STARCITIN Tablets above).

- The herbal remedy St John's Wort (*Hypericum perforatum*). This should not be taken at the same time as Citalopram.
- Monoamine oxidase inhibitors (MAOIs). These should not be taken at the same time as Citalopram (see Do not take STARCITIN Tablets above).

Tell your doctor if you are taking any of the following medicines:

- Sumatriptan (used to treat migraine) or tramadol (a pain killer). If you feel unwell when using these medicines with STARCITIN Tablets then you should see your doctor.
- Lithium (used to prevent and treat mania) and tryptophan (an anti-depressant)
- Medicines known to affect the blood platelets (e.g. anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac used as painkillers and some antipsychotic drugs and tricyclic antidepressants).
- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure. The effects of either drug could be increased, decreased or altered.
- Linezolid (an antibiotic).
- Imipramine and desipramine (used to treat depression).
- Medicines containing selegiline (used to treat Parkinson's disease)
- Cimetidine (used to treat stomach ulcers).
- Mefloquine (used to treat malaria).

- Bupropion (used to treat depression).
- Neuroleptics (used in the treatment of schizophrenia).

DO NOT TAKE STARCITIN TABLETS if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Taking STARCITIN Tablets with food and drink

STARCITIN Tablets can be taken with or without food.

As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment although STARCITIN Tablets has not been shown to increase the effects of alcohol.

Pregnancy

If you are pregnant, think you might be pregnant, or are trying to become pregnant, tell your doctor. Do not take STARCITIN Tablets if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

Make sure your midwife and/or doctor know you are on STARCITIN Tablets. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like STARCITIN Tablets may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Also, if you take Citalopram during the last 3 months of your pregnancy and until the date of birth you should be aware that the following effects may be seen in your newborn: fits, being too hot or cold, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, overactive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your newborn baby gets any of these symptoms please contact your midwife and/or doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

If you are breast-feeding, ask your doctor for advice. You should not breast-feed your baby while taking STARCITIN Tablets because small amounts of the medicine can pass into the breast milk.

Fertility

Citalopram has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

STARCITIN Tablets does not usually affect the ability to carry out normal daily activities. However if you feel dizzy or sleepy when you start to take this medicine, you should be careful when driving, operating machinery or performing jobs that need you to be alert until these effects wear off.

Important information about some of the ingredients of Citalopram Tablets

These tablets contain lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking STARCITIN Tablets.

3. HOW TO TAKE STARCITIN

Always take STARCITIN Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

Depression

The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

Panic disorder

The starting dose is 10 mg per day for the first week before increasing the dose to 20-30 mg per day. The dose may be increased by your doctor to a maximum of 40 mg per day.

Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 10-20 mg per day. Elderly patients should not usually receive more than 20 mg per day.

Children and adolescents (< 18 years)

STARCITIN Tablets is not recommended for children or adolescents. For further information, please see section 2, **Before you take STARCITIN Tablets.**

Patients with special risks

Patients with liver complaints should not receive more than 20 mg of STARCITIN Tablets per day.

How and when to take STARCITIN Tablets

STARCITIN Tablets is taken every day as a single daily dose. STARCITIN Tablets can be taken any time of the day with or without food. Swallow the tablets with a drink of water. Do not chew them (they have a bitter taste).

Duration of treatment

Like other medicines for depression and panic disorder these tablets may take a few weeks before you feel any improvement. Continue to take STARCITIN Tablets

even if it takes some time before you feel any improvement in your condition.

The duration of treatment is individual, usually at least 6 months. Continue to take STARCITIN Tablets for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Patients who have recurrent depression benefit from continued treatment, sometimes for several years, to prevent the occurrence of new depressive episodes.

Never change the dose of the medicine without talking to your doctor first.

If you have taken more STARCITIN Tablets than you should,

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. Always take any tablets left over with you, also the box and leaflet as this will allow easier identification of the tablets.

Symptoms of overdose may include:

- Nausea (feeling sick)
- Vomiting
- Sweating

- Drowsiness
- Seizures
- Unconsciousness
- Fast heart beats
- Tremor
- Irregular heart beat
- Changes in heart rhythm
- Changes in blood pressure
- Serotonin syndrome (see Section 4)
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly

If you forget to take STARCITIN Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with STARCITIN Tablets is stopped

Stopping this medicine quickly may cause symptoms such as dizziness, nausea and numbness or tingling in hands or feet, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). These symptoms are generally non-serious and disappear within a few days. When you have completed your course of treatment, the dose of Citalopram is usually reduced gradually over a couple of weeks.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, STARCITIN Tablets can have side effects and some people may experience unwanted effects (side effects) whilst taking Citalopram tablets. Several of the effects listed below can also be symptoms of your illness and may disappear as you start to get better.

Serious side effects

Stop taking STARCITIN Tablets and seek medical advice immediately if you suffer from any of the following allergic reactions:

- Difficulty in breathing.
- Swelling of the face, lips, tongue or throat that causes difficulty in swallowing or breathing.
- Severe itching of the skin (with raised lumps)
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as torsades de pointes.

If you notice any of the following symptoms you should stop taking STARCITIN Tablets and see your doctor immediately:

if you start having fits for the first time or fits that you have suffered from in the past become more frequent.

- if your behaviour changes because you feel elated or over excited.
- if you experience high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome.
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

The following side effects are often mild and usually disappear after a few days' treatment.

Very common side effects (likely to affect more than 1 in 10 people)

- Nausea (feeling sick),
- Dry mouth (a dry mouth increases the risk of tooth decay, so be sure to clean your teeth more often than usual),
- Increased sweating,
- Sleepiness,
- Difficulty in sleeping
- Headache

Common side effects (likely to affect up to 1 in 10 people)

- Lack of appetite
- Agitation
- Decreased sex drive
- Anxiety
- Nervousness
- Confusion
- Abnormal dreams
- Tremor
- Tingling or numbness in the hands or feet
- Ringing in the ears (tinnitus)
- Yawning
- Diarrhoea
- Vomiting
- Constipation
- Itching
- Pain in muscles and joints
- For men, problems with ejaculation and erection
- For females, failing to reach an orgasm
- Tiredness
- Prickling of the skin
- Loss of weight

Uncommon (likely to affect up to 1 in every 100 people)

- Bruising easily
- Increased appetite
- Aggression
- Reduced emotions, indifference
- Hallucinations
- Mania
- Fainting
- Large pupils (the dark centre of the eye)

- Fast heart beat
- Slow heart beat
- Nettle rash
- Loss of hair
- Rash
- Sensitivity to sunlight
- Difficulties urinating
- Vaginal bleeding
- Swelling of the arms or legs
- Increased weight

Rare (likely to affect up to 1 in every 1000 people)

- Convulsions
- Involuntary movements
- Taste disturbances
- Bleeding
- Hepatitis

Some patient have reported (frequency not known):

- Thoughts of harming or killing themselves
- An increase in bleeding or bruising caused by a decrease in blood platelets
- Rash (hypersensitivity)
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms
- Panic attack
- Grinding teeth
- Restlessness
- Unusual muscle movements or stiffness
- Involuntary movements of the muscles (akathisia)
- Low blood pressure
- Nosebleed
- Bleeding disorders including skin and mucosal bleeding (ecchymosis)
- Sudden swelling of skin or mucosa
- In men, painful erections
- Flow of breast milk in men or in women who are not breast-feeding (galactorrhoea)
- Abnormal liver function tests
- An increased risk of bone fractures has been observed in patients taking this type of medicines.

SSRIs can, very rarely, increase the risk of bleeding, including stomach or intestinal bleeding. Let your doctor know if you vomit blood or develop black or blood stained stools.

Also let your doctor know if you continue to have other symptoms associated with your depression. This might include hallucinations, anxiety, mania or confusion.

Very rarely, some patients may find that they have an increased tendency to develop rashes when exposed to the sun.

Any side effects that do occur will usually disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side effects while taking STARCITIN Tablets, please tell your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE STARCITIN

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions. Do not use your tablets after the expiry date stated on the label or carton.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.