

Talam

citalopram hydrobromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Talam. 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 Talam against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine.

You may need to read it again.

What Talam is used for

Talam contains the active ingredient citalopram (as citalopram hydrobromide) and is used to treat depression.

It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Ask your doctor if you have any questions about why Talam has been prescribed for you.

Your doctor may have prescribed Talam for another reason.

Talam is available only with a doctor's prescription.

There is no evidence that it is addictive.

Use in children and adolescents

Do not give Talam to children and adolescents under 18 years of age.

Talam is not recommended for use in children and adolescents under 18 years of age as the safety and efficacy in this age group has not been established.

Before you take it

When you must not take it

Do not take Talam if you have a heart condition called 'congenital long QT syndrome'. At high doses, Talam can cause changes in the way your heart beats.

See your doctor immediately if you experience an irregular heart beat, shortness of breath, dizziness or fainting while taking Talam.

Do not take Talam 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 which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Talam 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. Check with your doctor or pharmacist if you are

unsure as to whether or not you are taking an MAOI.

Taking Talam with MAOI 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 Talam after the MAOI has been stopped.

Do not take Talam if you are taking another medicine for psychotic disorder called pimozone.

If you take Talam while you are on pimozone, you may experience irregular pulses/heart beats.

Do not take the herbal remedy St. John's wort (*Hypericum perforatum*) at the same time as taking Talam.

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

It may not work as well if you do.

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

Before you start to take it

Tell your 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.

Do not take Talam if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

Make sure your doctor and/or midwife know you are on Talam.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like Talam

may affect the general condition of your newborn baby and may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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 doctor and/or midwife immediately.

If used during pregnancy, Talam should never be stopped abruptly.

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

Talam passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Talam when breastfeeding.

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

- a heart condition called ‘congenital long QT syndrome’. Your doctor may need to check your heart beat and rhythm periodically using an ECG test. The ECG test provides a record of the electrical activity of the heart.
- epilepsy or seizures
- diabetes
- liver disease
- kidney disease
- heart disease
- problems with blood clotting
- mania and/or bipolar disorder (manic/depressive illness).

Tell your doctor if you are receiving electroconvulsive therapy.

If you have not told your doctor about any of the above, tell them before you start taking Talam.

Taking other medicines

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

Some medicines may be affected by Talam or may affect how well it works. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression. You should stop taking MAOIs at least two weeks before starting Talam
- pimozide, a medicine used to treat psychotic disorders (disturbances in thinking, feelings and behaviour)
- St. John’s wort, a herbal remedy
- sumatriptan, used to treat migraine
- metoprolol, a medicine used to treat high blood pressure
- medicines used to treat reflux and ulcers including cimetidine and omeprazole
- selegiline, a medicine used to treat Parkinson’s disease
- warfarin, used to prevent blood clots
- lithium, used to treat mood swings and some types of depression
- carbamazepine, used to treat epilepsy
- tramadol, a medicine used to relieve pain
- some medicines used to treat fungal infections including ketoconazole and itraconazole
- macrolide antibiotics, used to treat infections such as erythromycin and clarithromycin
- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (NSAIDs)
- antipsychotics, medicines used to treat certain mental and emotional conditions
- other medicines to treat depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder.

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.

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 or antihistamines) should be avoided while taking Talam. If it is necessary to be on one of these medicines at the same time as Talam, your doctor may need to perform an ECG test to check your heart rate and rhythm.

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

How to take it

How much to take

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

The dose varies from patient to patient.

The usual starting dose is 20 mg (one tablet) per day. Your doctor may increase the dose slowly over several weeks depending on how you respond to this medicine. The maximum recommended dose is 40 mg (two tablets) per day.

The starting dose in elderly patients is 10 mg (half a tablet) per day and the maximum recommended dose is 20 mg (one tablet) per day.

If you have liver problems, or are taking medicines such as cimetidine or omeprazole the starting dose is 10 mg (half a tablet) per day and the maximum recommended dose is 20 mg (one tablet) per day.

Your doctor may have prescribed a different dose.

If you have been prescribed or are currently taking more than 40 mg of Talam a day, 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, Talam may not work as well and your condition may not improve.

How to take it

Swallow the tablets with a glass of water.

Talam should be taken either in the morning or evening, with or without food.

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

If you forget to take it

If you miss a dose and remember in less than 12 hours, take it straight away, and then continue as normal the next day.

Otherwise, skip the dose you missed, 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.

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

How long to take it

To properly control your condition, Talam must be taken exactly as your doctor has prescribed. If you do not follow your doctor's instructions, you may not get relief from your depression.

Keep taking Talam for as long as your doctor recommends.

Do not stop taking it even if you begin to feel better, unless you are told to do so by your doctor.

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

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full antidepressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Talam. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdosage may include nausea (feeling sick), vomiting, sweating, drowsiness, blue discolouration of the skin, convulsions or fits, unconsciousness, fast heart beats and tremor.

While you are taking it

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Talam.

Tell your doctor immediately if you become pregnant while taking Talam.

Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone taking Talam who talks about or shows signs of killing him or herself.

People taking Talam may be more likely to think about killing themselves or actually try to do so, especially when Talam is first started or the dose is changed.

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 during the first one to two months of taking Talam until the medicine starts to work completely. 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.

If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking Talam, contact a doctor immediately, or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Visit your doctor regularly so they can check on your progress.

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

All talk of suicide or violence must be taken seriously.

Tell your doctor immediately if you experience episodes of mania including a lot of rapidly changing thoughts or ideas, excessive physical activity and excessive restlessness.

Some patients with manic-depressive illness may enter a manic phase and experience these symptoms.

Things you must not do

Do not use Talam to treat any other conditions unless your doctor tells you to.

Do not suddenly stop taking Talam or lower the dose without checking with your doctor.

Stopping Talam suddenly may cause discontinuation symptoms such as dizziness, nausea and headache. When you have completed your course of treatment, the dose of Talam should be gradually reduced over a couple of weeks.

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

Things to be careful of

Be careful driving or operating machinery until you know how Talam affects you.

Talam may cause drowsiness, dizziness or lightheadedness in some people. Make sure you know how you react to Talam before you drive a car or operate machinery.

Talam has not been shown to increase the effects of alcohol. However, your doctor may suggest avoiding 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 Talam.

Talam helps most people with depression, but it may have unwanted side effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

- itching
 - ringing or a 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
 - increase or decrease in appetite
 - weight decrease or increase
 - nausea or vomiting
 - diarrhoea or constipation
 - increased flatulence (wind)
 - headache or migraine
 - yawning
 - dizziness
 - sleepiness or drowsiness, tiredness
 - a sense of indifference to everything
 - sexual disturbances (decreased sex drive, problems with orgasm, erection or ejaculation)
 - problems with menstrual period.
- Tell your doctor immediately if you notice any of the following:**
- chest pain
 - slow, fast or irregular heart beat
 - shortness of breath
 - dizziness when you stand up
 - 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

- bruising more easily than normal
- unusual bleeding, including bleeding from the stomach or bowel
- difficulty urinating or excess urine production
- tingling or numbness in the hands or feet
- agitation, nervousness, anxiety, confusion
- worsening of depression.

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

- thoughts of suicide or attempting suicide or self-harm
- shortness of breath or tightness in the chest
- aggressive behaviour
- tremors, involuntary movement of the muscles
- high fever, agitation, confusion, trembling and abrupt contraction of the muscles (symptoms of a rare condition called Serotonin Syndrome)
- fast, irregular heart beat with feelings of dizziness or difficulty breathing.

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

Other side effects not listed above may also occur in some patients.

An increased risk of bone fractures has been observed in patients taking medicines like Talam.

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

You may not experience any of them.

After taking it

Storage

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

Keep Talam 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.

Do not store Talam or any other medicine in the bathroom or near a sink.

Do not leave Talam in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Talam, 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

Talam 10 mg: white to off-white, round plain film-coated tablets. Available in blister pack of 28's.

Talam 20 mg: white, oval, film-coated tablet marked C|A on one side and blank on the other. Available in blister packs or bottles of 28 tablets.

Talam 40 mg: white to off-white, oval, biconvex film-coated tablets with 'BL' embossed on one side and '40' on the other. Available in blister pack of 28's.

Ingredients

Active ingredient:

Each tablet contains 10 mg, 20 mg or 40 mg of citalopram (as citalopram hydrobromide).

Inactive ingredients:

20 mg

- lactose
- cellulose-microcrystalline
- starch-maize
- povidone
- crospovidone
- magnesium stearate
- Opadry White complete film coating system Y-1-7000.

10 mg & 40 mg

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

The tablets are gluten-free.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

Australian Registration Numbers:

10 mg

Blister pack AUST R234594

20 mg

Blister pack AUST R 212219

Bottle AUST R 212220

40 mg

Blister pack AUST R 234596

This leaflet was revised in December 2015.