

Package leaflet: Information for the user

Citalopram Jubilant 10 mg film-coated tablets
Citalopram Jubilant 20 mg film-coated tablets
Citalopram Jubilant 30 mg film-coated tablets
Citalopram Jubilant 40 mg film-coated tablets

Citalopram (as hydrobromide)

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. See section 4.

What is in this leaflet

- 1. What Citalopram Jubilant is and what it is used for**
- 2. What you need to know before you take Citalopram Jubilant**
- 3. How to take Citalopram Jubilant**
- 4. Possible side effects**
- 5. How to store Citalopram Jubilant**
- 6. Contents of the pack and other information**

1. What Citalopram Jubilant is and what it is used for

How does Citalopram Jubilant work?

Citalopram Jubilant is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These drugs affect the serotonin system in the brain by increasing serotonin levels.

Citalopram Jubilant is used to treat depression and panic disorder, as well as prevention against relapse or new instances of depression.

Your doctor may have prescribed Citalopram Jubilant for any other disease. Ask your doctor if you have any questions about why Citalopram Jubilant has been prescribed for you.

2. What you need to know before you take Citalopram Jubilant

Do not take Citalopram Jubilant

- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6).
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and 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 you will need to wait 2 weeks before you start taking your Citalopram Jubilant tablets. One day must elapse after you have finished taking moclobemide. After stopping Citalopram Jubilant 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 (see section 'Other medicines and Citalopram Jubilant' below).

Warnings and precautions

Talk to your doctor or pharmacist before taking Citalopram Jubilant in case you:

- Suffer from diabetes, treatment with Citalopram Jubilant may alter control of your sugar levels.
- Suffer from epilepsy or seizures, as seizures are a potential risk with antidepressant drugs.
- have received electro-convulsive therapy.
- Have a history of mania/hypomania, Citalopram Jubilant should be used with caution and should be discontinued when you enter a manic phase.
- Have kidney or liver problems. Citalopram Jubilant is not recommended for use in patients with severe kidney problems.
- have an increased tendency to bleed, or if you are pregnant (see "Pregnancy, breastfeeding and fertility")
- use medicines that affect the ability of the blood to clot (see "Other medicines and Citalopram Jubilant")
- Suffer from low blood sodium levels.
- Suffer from psychosis with depressive episodes.
- 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.
- If you have problems with your eyes, such as certain kinds of glaucoma.

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

Please note:

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.

Medicines like Citalopram Jubilant (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

If you start to feel worse and have thoughts of harming yourself

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.

Children and adolescents

Citalopram Jubilant should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 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 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram Jubilant for a patient under 18 and 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 are taking Citalopram Jubilant. 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.

Other medicines and Citalopram Jubilant

Tell your doctor or pharmacist if you are taking, have taken or might take any other medicines. The treatment effect can be affected if this medicine is taken at the same time as certain other medicines.

Be especially careful to inform your doctor about the following medications:

- Non-selective monoamine oxidase inhibitors (MAO inhibitors) containing phenelzine, iproniazid, isocarboxazid, nialamide and tranylcypromine as active substance. If you have taken any of these medicine, you must wait 14 days before starting Citalopram Jubilant . After completion of treatment with Citalopram Jubilant you must wait 7 days before taking any of these medicines

These should not be taken at the same time as Citalopram Jubilant (see **Do not take Citalopram Jubilant**)

Be especially careful to inform your doctor about the following medications:

- Linezolid (an antibiotic).
- Lithium (used to prevent and treat mania) and tryptophan (an antidepressant).
- Reversible, selective MAO-A inhibitors containing moclobemide (medicine against depression).
- Imipramine and desipramine (drugs for depression).
- Irreversible MAO-B inhibitors containing selegiline (medicine against Parkinson's disease). These increase the risk of side effects.
- Metoprolol (medicine against high blood pressure and cardiovascular diseases). The dose of Citalopram Jubilant may need to be adjusted.
- Sumatriptan and similar medicines (anti-migraine medicines) and tramadol and similar medicines (opioids, medicines for severe pain). These increase the risk of side effects.
- Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), and fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of blood clots). These can cause increased levels of citalopram in the blood.
- Medicines that increase the risk of bleeding, e.g. anticoagulants (medicines that inhibit the blood's ability to clot), NSAIDs (medicines for pain and/or inflammation) (eg ticlopidine and dipyridamole) and salicylic acid derivatives (eg acetylsalicylic acid) can cause skin and mucosal bleeding if given at the same time with Citalopram Jubilant .
- (Traditional) herbal medicines containing St. John's wort (*Hypericum perforatum*). St. John's wort may increase the risk of side effects.
- Mefloquine (medicine against malaria) and bupropion (medicine against depression and smoking cessation) due to a possible risk of lowering the seizure threshold.

Neuroleptics (drugs against schizophrenia, psychosis) due to a possible risk of lowering the seizure threshold, and antidepressants. • Medicines that lower blood levels of potassium or magnesium, as these conditions increase the risk of serious heart rhythm disturbances.

Do not take Citalopram Jubilant 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. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor

Citalopram Jubilant with food, drink and alcohol

Citalopram Jubilant can be taken with or without food (see section 3).

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Abrupt discontinuation of treatment should be avoided during pregnancy.

Pregnancy

Make sure your midwife and/or doctor know you are on Citalopram Jubilant. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Jubilant 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 midwife and/or doctor immediately. Also, if you are taking Citalopram Jubilant in the last 3 months of pregnancy, let your doctor know as your baby might have some symptoms when it is born. These symptoms usually begin during the first 24 hours after the baby is born. They include not being able to sleep or feed properly, trouble with breathing, a blue-ish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, tremors, jitters or fits. If your baby has any of these symptoms when it is born, contact your doctor who will be able to advise you.

If you take Citalopram Jubilant near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Citalopram Jubilant so they can advise you.

Breast-feeding

Citalopram Jubilant passes into breast milk in small amounts. There is a risk of an effect on the baby. If you are taking Citalopram Jubilant, talk to your doctor before you start breast-feeding.

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

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.

Driving and using machines

Citalopram Jubilant 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.

Citalopram Jubilant contains lactose and sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Citalopram Jubilant contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Citalopram Jubilant

How much to take

Always take this medicine exactly as your doctor or pharmacist has told you. 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 (> 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.

Use in Children and adolescents

Citalopram Jubilant should not be used in the treatment of children and adolescents under 18 years of age. (see 'Warnings and precautions').

Patients with special risks

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

How and when to take Citalopram Jubilant

Citalopram Jubilant is taken every day as a single daily dose. Citalopram Jubilant can be taken any time of the day with or without food. Swallow the tablets with a drink of water.

Duration of treatment

Like other medicines of this type, Citalopram Jubilant does not provide immediate relief of symptoms, but generally only after a few weeks. Do not change the dosage without first talking to your doctor. Continue to take Citalopram Jubilant for as long as your doctor recommends. If you stop the treatment too soon, the symptoms may return. It is recommended that you continue treatment for at least 6 months after you feel well again. The underlying disease may remain for a longer period of time and if you stop the treatment too soon, the symptoms may return. Patients with recurrent depression may need to be treated for several years to avoid relapse .

If you take more Citalopram Jubilant than you should

If you have taken too much medicine or if e.g. a child has ingested the medicine by mistake, contact a doctor, hospital or the Poisons Information Center (tel. 112) for an assessment of the risk and advice. Do this even if you/the child do not notice any symptoms. If you go to the doctor or hospital, take the Citalopram Jubilant pack with you.

Symptoms of overdose may include:

- Irregular heart beat
- Seizures
- Changes in heart rhythm
- Feeling sick (nausea)
- Vomiting
- Sweating
- Drowsiness
- Coma
- Fast heart beats

- Tremor
- Changes in blood pressure
- Serotonin syndrome (see Section 4)
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly

If you forget to take Citalopram Jubilant

If you miss a dose, do not take a double dose to make up for a forgotten dose. If you forget to take a dose and you remember before going to bed, take the dose at once. Continue as usual the next day. If during the night or the next day you realize you have forgotten a dose, then skip the missed dose and continue as usual.

If you stop taking Citalopram Jubilant

Do not stop taking Citalopram Jubilant unless you are told to do so by your doctor. Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks.

Withdrawal symptoms seen on discontinuation

Withdrawal symptoms at the end of treatment So-called withdrawal symptoms are common when treatment with Citalopram Jubilant is ended. The risk may be increased if Citalopram Jubilant has been used for a longer time or in higher doses, or if the dose has been reduced too quickly. In the majority of cases, these symptoms are transient within two weeks. Your doctor may advise you to reduce the dose gradually. If it is not reduced gradually, the risk of withdrawal symptoms is greater. Contact a doctor if you experience severe withdrawal symptoms after completing treatment. The doctor may ask you to start taking the tablets again, and then withdraw them more slowly. If you experience withdrawal symptoms, this does not mean that you are addicted or will not be able to stop taking Citalopram Jubilant . Withdrawal reactions include: dizziness, pins and needles, electric shock sensations, numbness, sleeplessness, intense dreams, agitation, anxiety, feeling sick or being sick, shaking, confusion, sweating, headache, diarrhoea, faster heartbeat (palpitations), emotional instability, irritability and visual disturbances. Most of the withdrawal reactions are mild and self-limiting in nature but may be severe in some patients.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. A few people may develop a severe allergic reaction. This is a very rare but serious side effect.

If you experience any of the following symptoms stop taking Citalopram Jubilant and tell your doctor immediately:

Not known (frequency cannot be estimated from the available data)

- High fever, anxiety, confusion, tremors and sudden muscle contractions: may be signs of a rare condition called serotonin syndrome which has been reported with concomitant use of several drugs for depression.

- If you experience swelling of the skin, lips, face, tongue or throat (angioedema) leading to severe difficulty in swallowing or breathing.
- Bleeding in the stomach or intestines.
- Fast, irregular heartbeat and fainting, which can be symptoms of a life-threatening condition known as Torsade de Pointes.

Rare (may affect up to 1 in 1,000 users)

- Hyponatremia: low blood levels of sodium which can cause tiredness, confusion and muscle twitching.

The following side effects are usually mild and disappear after a few days of treatment. Attention that several of the symptoms may also be due to your illness and will therefore subside when you start to feel better. Contact your doctor if any of the side effects are bothersome or last longer than a few days.

Dry mouth increases the risk of caries. You should brush your teeth more often than usual.

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

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

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

- Loss of appetite
- Agitation
- Decreased sex drive
- Anxiety
- Nervousness
- Confusion
- Abnormal dreams (unusual and intense 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
- Loss of weight
- Problems with concentration

- Absence of emotion or enthusiasm
- Dizziness
- Blocked or runny and itchy nose
- Indigestion/heart burn
- Stomach pain
- Wind (Flatulence)
- Increased saliva

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

- Bruising easily
- Increased appetite
- Aggression
- Depersonalization (feeling disconnected or detached from body and thoughts)
- Hallucinations
- Mania
- Fainting
- Large pupils (the dark centre of the eye)
- Fast heart beat
- Slow heart beat
- Nettle rash
- Loss of hair
- Coughing
- Rash
- Sensitivity to sunlight
- Difficulties urinating
- Abnormally heavy and prolonged menstrual period
- Swelling of the arms or legs
- Increased weight
- Feeling unwell (malaise)

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

- Convulsions
- Involuntary movements
- Taste disturbances
- Bleeding
- Inflammation of the liver (hepatitis)
- Fever

Not known (frequency cannot be estimated from the available data)

Thoughts of harming or killing themselves, see also section 2 “What you need to know before you take Citalopram Jubilant”

- An increase in bleeding or bruising caused by a decrease in blood platelets (thrombocytopenia)
- Low potassium levels in the blood
- Panic attack
- Grinding teeth
- Restlessness
- Unusual muscle movements or stiffness

- Involuntary movements of the muscles (akathisia)
- 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
- Increased urine volume
- Visual disturbance
- Low blood pressure
- An increased risk of bone fractures has been observed in patients taking this type of medicines
- Abnormal heart rhythm
- Irregular menstrual bleeding
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information

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

Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks.

Withdrawal reactions include: dizziness, pins and needles, electric shock sensations, numbness, sleeplessness, intense dreams, agitation, anxiety, feeling sick or being sick, shaking, confusion, sweating, headache, diarrhoea, faster heartbeat (palpitations), emotional instability, irritability and visual disturbances. Most of the withdrawal reactions are mild and self limiting in nature.

Any side effects that do occur will usually disappear after a few days.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Citalopram Jubilant

- Keep this medicine out of the sight and reach of children.
- This medicine does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Citalopram Jubilant contains

- The active substances is citalopram. Each Citalopram Jubilant tablet contains 10 mg, 20 mg, 30 mg or 40 mg citalopram (as hydrobromide).
- The other ingredients are:
microcrystalline cellulose (E460), lactose monohydrate, copovidone (E1201), croscarmellose sodium (E468), maize starch, magnesium stearate (E470b), hypromellose (E464), glycerol (E422), titanium dioxide (E171), macrogol (E1521).

What Citalopram Jubilant looks like and contents of the pack

Citalopram Jubilant is presented as 10mg, 20mg, 30mg and 40mg film-coated tablets. The tablets are described below.

Citalopram Jubilant 10mg: White, round, film-coated tablets of approximately 5,60 mm diameter, debossed with 'F7' on one side and plain on the other side.

Citalopram Jubilant 20 mg: White oval shaped, biconvex, film-coated tablets of approximately 8,15 mm length and 5,65 mm width, with scoreline on one side, debossed with 'F' on the left side and '8' on the right side of the scoreline and plain on the other side.

Citalopram Jubilant 30 mg: White, modified capsule shaped, biconvex, film-coated tablets of approximately 11,15 mm length and 5,65 mm width, with scoreline on both sides, debossed with 'F' and '9' on either side of the scoreline on one side of the tablets.

Citalopram Jubilant 40 mg: White oval shaped, biconvex, film-coated tablets of approximately 11,65 mm length and 7,15 mm width, with scoreline on one side, debossed with 'G' on the left side and '1' on the right side of the scoreline and plain on the other side.

Citalopram Jubilant is available in the following pack sizes:

Alu/PVC/PVDC blister in cardboard box

20, 28, 30, 50, 56, 84, 90, 98 and 100 tablets

Alu/Alu blisters in cardboard box

20, 28, 30, 50, 56, 84, 90, 98 and 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

PSI supply nv

Axxes Business Park

Guldensporenpark 22 – Block C

9820 Merelbeke

Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	:	Citalopram Jubilant 10 – 20 – 30 – 40 mg Filmovertrukket tablet
Sweden	:	Citalopram Jubilant 10 – 20 – 30 – 40 mg Filmdragerad tablett

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