Pharma code

Pharma code

150 mm

Pharma code

Citalopram 10mg film-coated Tablets

Citalopram 20mg film-coated Tablets

Citalopram 30mg film-coated Tablets

Citalopram 40mg 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 onto 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 Citalogram tablets are and what they are used for 2. What you need to know before you take Citalopram tablets

3. How to take Citalogram tablets 4. Possible side effects

5.How to store Citalopram tablets

6. Contents of the pack and other information

1. What Citalopram tablets are and what they are used for

How does Citalopram tablets work? Citalopram is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

What Citalopram tablet is used for? Citalopram tablets contains citalopram and is used taking, have taken or might take any other for the treatment of depression and, when you feel medicines. This includes other medicines for better, to help prevent these symptoms recurring. Citalopram tablets is also used for long term treatment to prevent the occurrence of new episodes of depression if you have recurrent

Citalopram tablets is also beneficial in relieving symptoms if you tend to suffer from panic attacks.

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

DO NOT take Citalopram tablets:

if you are allergic to Citalopram tablets or to any of the other ingredients of this medicine (listed in section 6). Consult your doctor if you think you might be.

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).

at the same time as taking medication known as

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 tablets. One day must elapse after you have finished

taking moclobemide. After stopping Citalopram

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 (see Other medicines and Citalopram tablets below).

Warnings and precautions

Please tell your doctor if you have any medical problems, especially if you have

• History of bleeding disorders or have ever suffered from bleeding in the stomach or intestine, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').

• Liver disease.

 Kidney disease. • Diabetes (you may need an adjustment of your

antidiabetic therapy).

Epilepsy or a history of seizures or fits. Mania or panic disorder Low blood levels of sodium

recently had a heart attack.

• ECT (electroconvulsive therapy) • Suffered or suffer from heart problems or 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). Experienced a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may

indicate abnormal functioning of the heart rate. If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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

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

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 tablets treatment it may take several weeks before you experience any improvement. In during pregnancy, particularly in the last 3 months the beginning of the treatment certain patients may of pregnancy, medicines like Citalopram tablets 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

Thoughts of suicide and worsening of your depression or anxiety disorder

dose without consulting your doctor.

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 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 Fertility **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 Citalopram tablets 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. Important information about some of the Despite this, your doctor may prescribe Citalopram tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalogram tablets 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 tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram tablets in this age group have not yet been demonstrated.

Other medicines and Citalopram tablets Medicines may affect the action of other medicines and this can sometimes cause serious

adverse reactions. Please tell your doctor or pharmacist if you are

depression (see "Do not take Citalopram tablets") • The herbal remedy St John's wort (Hypericum perforatum). This should not be taken at the same time as Citalopram tablets.

Monoamine oxidase inhibitors (MAOIs). These should not be taken at the same time as Citalopram tablets (see Do not take Citalopram

Tell your doctor if you are taking any of the following medicines: Linezolid (an antibiotic).

Sumatriptan (used to treat migraine) or tramadol and buprenorphine and similar medicines (strong pain killers). Taking these medicines together with Citalopram tablets can lead to serotonin syndrome, a potentially life-threatening condition The syndrome may be associated with symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such

symptoms Lithium (used to prevent and treat mania) and tryptophan (an antidepressant).

Pimozide (a neuroleptic). This should not be taken at the same time as Citalopram tablets • Imipramine and desipramine (used to treat

• Medicines containing selegiline (used to treat Parkinson's disease).

Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine

(antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Citalopram tablets. Mefloquine (used to treat malaria).

· Bupropion (used to treat depression). Medicines known to affect the blood platelets (e.g. anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal antiinflammatory 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. Neuroleptics (used in the treatment of schizophrenia).

Do not take Citalopram 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. 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.

Taking Citalopram tablets with food, drink and alcohol

Citalopram tablets can be taken with or without food (see section 3 "How to take Citalogram tablets"). As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment although Citalogram tablets has not been shown to increase the effects of alcohol. Pregnancy

If you take Citalopram tablets 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 tablets so they can advise you. Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, think you might be pregnant, or are trying to become pregnant, tell your doctor. Do not take Citalopram 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 Citalopram tablets. When taken 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 tablets 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 new born baby gets any of these symptoms please contact your midwife and/or doctor immediately. **Breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. If you are breast-feeding, ask your doctor for advice. You should not breast -feed your baby when taking Citalopram tablets because small amounts of the medicine can pass into the breast milk.

Citalopram tablets has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human

Driving and using machines

Citalogram 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.

ingredients of Citalopram tablets Information about sodium content

This medicine contains less than 1 mmol sodium

(23 mg) per tablet, that is to say essentially sodium-free'. This product contains lactose.

If you have been told by your doctor that you have

an intolerance to some sugars, contact your doctor Yawning before taking this medicinal product.

3. How to take Citalopram tablets

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.

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 (less than 18 years of age) Citalopram tablets should not be given to children or adolescents. For further information, please see section 2, What you need to know

before you take Citalopram tablets. Patients with special risks

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

How and when to take Citalopram tablets. Citalopram tablets is taken every day as a single daily dose. Citalopram 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 Citalopram 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 the 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 take more Citalopram tablets than you **should** If you think that you or anyone else may have taken too many Citalopram tablets contact your doctor or nearest hospital emergency

department immediately. Do this even if there are no signs of discomfort or poisoning. Take the Citalogram tablets box/ container with you if you go to a doctor or hospital. Some of the signs of an overdosage could be life-threatening.

Symptoms of overdosage may include: Irregular heart beat

• Changes in heart rhythm • Feeling sick (nausea)

 Vomiting Sweating

Drowsiness

 Unconsciousness 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 tablets

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose. Effects when treatment with Citalopram 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 are usually nonserious and disappear within a few days. When you have completed your course of treatment, the dose of Citalopram tablets 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 this medicine can cause side effects, although not everybody gets them. Several of the effects listed below can also be symptoms of your illness and may disappear as you start to

Serious side effects Stop taking Citalopram tablets and seek medical

advice immediately if you have any of the following symptoms: 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 heartbeat, 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 contact your doctor immediately as your dose may need to be reduced or stopped: You start having fits for the first time or fits that you have suffered from in the past become more frequent.

Your behaviour changes because you feel elated 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

These may be signs of a low blood level of sodium (hyponatraemia).

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 (may affect more than 1 in 10 people) Sleepiness

 Difficulty in sleeping Headache

Changes in your sleeping pattern Loss of body strength, weakness 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) Common side effects (may affect up to 1 in 10

people) Lack of appetite

 Agitation Decreased sex drive

Anxiety

Nervousness Confusion

 Abnormal dreams Reduced emotions, indifference (apathy)

 Tremor Tingling or numbness in the hands or feet Dizziness

 Problems concentrating Migraine

Loss of memory (amnesia)

Ringing in the ears (tinnitus) Palpitations

Blocked or runny nose (rhinitis)

Diarrhoea

Vomiting Constipation Stomach pain

 Flatulence (wind) Increase in saliva (drooling) Itching

• Pain in muscles and joints For men, problems with ejaculation and erection For women, failing to reach an orgasm

Tiredness Prickling of the skin

Loss of weight

Uncommon (may affect up to 1 in 100 people) Bruising easily

Increased appetite Aggression

 Hallucinations Mania

Fainting • Large pupils (the dark center of the eye)

Fast heart beat Slow heart beat Nettle rash

Loss of hair Rash Sensitivity to sunlight

Difficulties urinating Excessive menstrual bleeding • Swelling of the arms or legs

 Increased weight Rare (may affect up to 1 in 1000 people)

 Increased sex drive Convulsions Involuntary movements

Taste disturbances

Feeling unwell (malaise)

 Bleeding Coughing Hepatitis

Some patient have reported (frequency not known) Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more

information. Thoughts of harming or killing themselves, see also section 2 "What you need to know before you take Citalopram tablets"

An increase in bleeding or bruising caused by a

decrease in blood platelets (thrombocytopenia) Rash (hypersensitivity) Low potassium levels in the blood (hypokalaemia), which can cause muscle

weakness, twitching or abnormal heart rhythms Increase in a hormone called prolactin in the blood

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) Irregular menstrual periods Abnormal liver function tests • An increased risk of bone fractures has been

observed in patients taking this type of medicines

 Abnormal heart rhythm 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. 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 Citalopram tablets, please tell your doctor. Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible

side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website:www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Citalopram tablets · Always keep this medicine out of the sight and reach of children. • Store your tablets at or below 25°C.

which is stated on the label or carton. 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 to protect the environment.

6. Contents of the pack and other information

film-coated tablets in four different strengths. Each

What Citalopram tablets contains

The active substance is Citalopram (as

hydrobromide). Citalopram is produced as

• Do not use this medicine after the expiry date

Citalopram film-coated tablets contains 10 mg/ 20mg/30mg/40mg Citalopram. The other ingredients are: Tablet core: maize starch, lactose monohydrate, microcrystalline cellulose, copovidone, glycerol

85%, croscarmellose sodium and magnesium stearate.

Citalopram 10 mg film-coated tablets are white

to off white round biconvex film coated tablets

Tablet coating: Hypromellose (E464), Macrogol 400 and Titanium dioxide (E 171). What Citalopram tablets looks like and contents of the packs

plain on both side. Citalopram 20 mg film-coated tablets are white to off white oval biconvex film coated tablets debossed with "C 20" on one side and score notch on other side. Citalopram 30 mg film-coated tablets are white to off white, round, film coated tablets debossed with "C" and "30" separated by breakline on one side and plain on other side. Citalopram 40 mg film-coated tablets are white to off white oval biconvex film coated tablets debossed with "40" on one side and breakline on other side. Citalopram 10mg, 20mg, 30mg and 40mg film-coated tablets are available in cartons containing Aluminium-PVC/PVDC blister

packs of 28's along with a leaflet inside. Marketing Authorization Holder Flamingo Pharma (UK) Ltd. 1st Floor, Kirkland House, 11-15 Peterborough Road,

Harrow, Middlesex, HA1 2AX, United Kingdom. Manufacturer Flamingo Pharma (UK) Ltd. The Bloc, 38 Springfield Way,

Anlaby, Hull, HU 10 6RJ, United Kingdom Citalopram tablets 10 mg film-coated tablets (PL 43461/0129) Citalopram tablets 20 mg film-coated tablets (PL 43461/0130)

Citalopram tablets 30 mg film-coated tablets

Citalopram tablets 40 mg film-coated tablets

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