

Package leaflet: Information for the user

Paroxetine 20 mg and 30 mg Film-Coated Tablets

Paroxetine

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

1. What Paroxetine is and what it is used for

- Paroxetine belongs to a group of drugs called selective serotonin re-uptake inhibitors (SSRIs). Serotonin is a chemical that, in the brain, passes messages between nerve cells and may help to control mood. Paroxetine brings the level of serotonin back to normal.
- Paroxetine is used to treat the symptoms, and prevent a recurrence of, depression and any accompanied anxiety, obsessive compulsive disorder (OCD), panic attacks (with or without agoraphobia – fear of going into public places) and generalised anxiety disorder. It is also used to treat social anxiety disorder (social phobia).

2. What you need to know before you take Paroxetine

Do not take Paroxetine:

- If you are allergic to paroxetine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking thioridazine, used in the treatment of schizophrenia
- If you are taking pimozide, used to treat schizophrenia and other mental illnesses
- If you are taking, or have taken in the past 2 weeks, a monoamine oxidase inhibitor (MAOI) also used to treat depression, e.g. selegiline
- At least 24 hours after discontinuing a reversible MAOI e.g. methylene blue or linezolid or moclobemide.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Paroxetine.

- If you have a history of mania (periods of unusually elevated high mood and activity)
- If you have kidney, liver or heart problems
- If you have a history of bleeding disorders or a tendency to bleed
- If you have epilepsy or a history of fits
- If you have diabetes
- If you have glaucoma (increased pressure in the eye)
- If you have been told that you have low levels of sodium
- If you are due to receive electro-convulsive therapy (ECT).

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 young adults (less than 25 years old) 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.

Other medicines and Paroxetine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Check with your doctor if you are taking any of the following:

- Other antidepressants including other SSRIs, tryptophans and tricyclic antidepressants such as clomipramine, nortriptyline and desipramine
- The herbal remedy St John's Wort (*Hypericum perforatum*), used to treat depression
- Medicines such as lithium, risperidone, perphenazine, phenothiazine and clozapine (known as anti-psychotics), atomoxetine used to treat some psychiatric conditions
- Phenobarbital, phenytoin or carbamazepine, sodium valproate used to treat fits or epilepsy
- Procyclidine (used to relieve tremor, especially in Parkinson's Disease)
- Aspirin, ibuprofen, or other medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) such as celecoxib, etodolac, meloxicam and refecoxib that are used to treat pain and inflammation
- Tramadol, fentanyl, pethidine (painkillers)
- Medicines called triptans, such as sumatriptan (used to treat migraine)
- Medicines used to thin the blood (anticoagulants), such as warfarin
- Medicines used to treat an irregular heartbeat, such as propafenone and flecainide
- Metoprolol, a beta-blocker used to treat high blood pressure and heart problems
- Pravastatin, used to treat high cholesterol
- Rifampicin (used to treat tuberculosis (TB) and leprosy)
- Fosamprenavir, ritonavir, used in treating HIV infection
- Tamoxifen, used for breast cancer or fertility
- Linezolid (an antibiotic)
- Pimozide (a medicine for mental disorders such as psychosis)
- Methylene blue (a pre-operative visualising agent).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Paroxetine with food and drink and alcohol

You are advised not to drink alcohol whilst taking these tablets.

Pregnancy, breast-feeding 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.

This is because some studies have suggested an increase in the risk of heart defects in babies whose mothers received Paroxetine in the first few months of pregnancy. These studies found that less than 2 in 100 babies

(2%) whose mothers received Paroxetine in early pregnancy had a heart defect, compared with the normal rate of 1 in 100 babies (1%) seen in the general population. You and your doctor may decide that it is better for you to gradually stop taking Paroxetine while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Paroxetine.

If you are taking Paroxetine in the last 3 months of pregnancy, let your midwife 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 and you are concerned, contact your doctor or midwife who will be able to advise you.

Make sure your midwife and/or doctor know you are on Paroxetine. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Paroxetine 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.

Paroxetine may get into breast milk in very small amounts. If you are taking Paroxetine, go back and talk to your doctor before you start breastfeeding.

Paroxetine 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

Your tablets may make you feel sleepy or dizzy. Do not drive or operate machinery if you are affected.

3. How to take Paroxetine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the tablets each morning with food. The tablets should be swallowed whole with a drink of water and not chewed.

The usual dose is:

Adults

Depression and social anxiety disorder (social phobia):

One 20 mg tablet daily. Where necessary your doctor may increase this to a maximum of 50 mg daily.

Obsessive compulsive disorder (OCD):

40 mg daily. Your doctor will start you on a lower dose and increase this gradually. The maximum dose is 60 mg a day.

Panic disorder:

40 mg daily. Your doctor will start you on a dose of 10 mg a day and increase this gradually. The maximum dose is 60 mg daily.

Generalised anxiety disorder:

One 20 mg tablet daily. Your doctor may increase your doses gradually up to a maximum dose of 50 mg a day.

Older people

Your doctor will start you on the normal adult dose which he may increase up to a maximum of 40 mg a day.

Patients with severe liver or kidney problems

The recommended dose is 20 mg per day.

Use in children and adolescents

Not recommended.

Paroxetine will not relieve your symptoms straight away. You should start to feel better after a week or two, although it may take longer.

If you take more Paroxetine than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause nausea, vomiting, shaking, dilated pupils, dry mouth, irritability, sweating and insomnia. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Paroxetine

If you do forget a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day.

If you only remember during the night, or the next day, leave out the missed dose. You may possibly get withdrawal effects, but these should go away after you take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Paroxetine

Do not stop taking your tablets suddenly. When your doctor decides to stop your tablets, your dose will be reduced gradually over a number of weeks or months to help reduce the chance of withdrawal effects.

If you get withdrawal effects when you are coming off your tablets your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking Paroxetine, please see your doctor, who may ask you to start taking your tablets again and come off them more slowly. If you do get withdrawal effects, you will still be able to stop Paroxetine.

*Possible withdrawal effects when stopping treatment:**Common (affecting fewer than one person in 10 but more than one person in 100):*

- Feeling dizzy, unsteady or off-balance
- Pins and needles, electric shock sensations, ringing in the ears (tinnitus)
- Sleep disturbances (vivid dreams, nightmares, inability to sleep)
- Feeling anxious
- Headaches.

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):

- Feeling sick, diarrhoea
- Sweating
- Feeling restless or agitated
- Tremor (shakiness)
- Feeling confused
- Feeling emotional or irritable
- Visual disturbances
- Fluttering or pounding heartbeat (palpitations).

Generally these side effects are mild and do not last for a very long time but in some people they may be more serious or last longer.

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

4. Possible side effects

Like all medicines, Paroxetine can cause side effects, although not everybody gets them.

If you experience the following, stop taking Paroxetine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A severe allergic reaction (red and lumpy skin rash, itching, swelling of the eyelids, face, lips, mouth or tongue, throat or have difficulty breathing (shortness of breath) or swallowing and feel weak or lightheaded resulting in collapse or loss of consciousness.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Very common (may affect more than 1 in 10 people):

- Inability to concentrate
- Feeling sick
- Change in sex drive or sexual function, for example, lack of orgasm and, in men, abnormal erection and ejaculation.

Common (may affect up to 1 in 10 people):

- Decreased appetite
- Not sleeping well (insomnia) or feeling sleepy
- Feeling dizzy or shaky
- Lack or loss of strength and energy, weakness
- Blurred vision
- Yawning, dry mouth, vomiting, increased appetite
- Sweating
- Diarrhoea or constipation
- Abnormal dreams including nightmares
- High levels of cholesterol
- Agitation
- Headache
- Weight gain.

Uncommon (may affect up to 1 in 100 people):

- Unusual bruising or bleeding
- Feeling confused or having hallucinations
- Impairment of voluntary movement, tremors, tics, abnormal movements in the mouth and tongue changes in muscle tone, slowness of movement
- Brief increase or decrease in blood pressure, a faster than normal heartbeat
- Skin rashes, itching
- Prolonged enlargement of the pupil (Mydriasis)
- Low blood pressure with dizziness when you stand rapidly (Postural hypertension)
- Involuntary leakage of urine
- Inability or difficulty in urinating (passing water)
- If you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking Paroxetine. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.

Rare (may affect up to 1 in 1,000 people):

- Low blood levels of sodium, which can cause tiredness and confusion, muscle twitching, fits or coma
- Overactive behaviour or thoughts (mania), agitation, anxiety, a feeling of things being unreal, panic attacks, feeling restless and like you can't sit or stand still

- Fits (convulsions)
- A slow heartbeat
- Effects on the liver that show up in blood tests of your liver function
- Production of breast milk in both men and women
- Pain in the joints or muscles.
- Restless legs syndrome (a condition where your legs feel extremely uncomfortable when resting i.e. sitting or lying down)

Very rare (may affect up to 1 in 10,000 people):

- Increased bleeding, reduction in blood platelets, which increases risk of bleeding or bruising
- Allergic reaction including nettle rash and swelling of the face, lips, mouth or throat
- A condition known as syndrome of inappropriate anti-diuretic hormone secretion (SIADH), the symptoms of which include weight gain, feeling or being sick, muscle cramps, confusion and fits
- A condition known as serotonin syndrome, the symptoms of which include agitation, confusion, sweating, hallucinations, sudden jerks of the muscles, shivering, a fast heartbeat and shaking
- Acute glaucoma - the symptoms are painful eyes and blurred vision
- Inflammatory skin eruption
- Serious illness with blistering of the skin, mouth, eyes and genitals
- Skin reactions caused by exposure to sunlight
- Painful erection of the penis that won't go away
- Fluid or water retention which may cause swelling of the arms or legs
- Liver problems that make the skin or whites of the eyes go yellow.

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

- Aggression
- Tooth grinding

The following side effects have also been reported.

- Suicidal behaviour and ideas
- Ringing in the ears

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

Additional side effects in children and adolescents

Paroxetine should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine for this age group. Also, patients under 18 have an increased risk of side-effects such as suicidal thoughts and harming themselves when they take Paroxetine. If your doctor has prescribed Paroxetine for you (or your child) and you want to discuss this, please go back to your doctor.

In studies of Paroxetine in under 18s, common side-effects that affected less than 1 in 10 children/adolescents were: an increase in suicidal thoughts and suicide attempts, deliberately harming themselves, being hostile, aggressive or unfriendly, lack of appetite, shaking, abnormal sweating, hyperactivity (having too much energy), agitation, changing emotions (including crying and changes in mood). These studies also showed that the same symptoms affected children and adolescents taking sugar pills (placebo) instead of Paroxetine, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects when they stopped taking Paroxetine. These effects were mostly similar to those seen in adults after stopping Paroxetine. In addition, patients under 18 also commonly (less than 1 in 10) experienced stomach ache, feeling nervous and changing emotions (including crying, changes in mood, trying to hurt themselves, thoughts of suicide and attempting suicide).

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 Yellow Card Scheme at: 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 Paroxetine

Keep this medicine out of the sight and reach of children. Store in the original package. Do not use Paroxetine after the expiry date shown on the outer packaging.

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 Paroxetine contains:

- The active substance is paroxetine (as hydrochloride hemihydrate), 20 mg or 30 mg
- The other ingredients are calcium phosphate, povidone, sodium starch glycolate, magnesium stearate, titanium dioxide (E171), methylcellulose, macrogol and polysorbate.

What Paroxetine looks like and contents of the pack:

- Paroxetine 20 mg Film-Coated Tablets are white to off-white, round biconvex film-coated tablets, 8.0 mm in diameter, scored on one side and debossed with "2" on one side of the score and "0" on the other side of the score. The other side of the tablet debossed with "PX". The tablet can be divided into equal halves.
- Paroxetine 30 mg Film-Coated Tablets are white to off-white, round biconvex film-coated tablets, embossed with "30" and scored on one side and with "PX" on the other side
- The 20 mg tablets are available in pack sizes of 14, 20, 28, 30, 50, 56, 60, 84 and 100 tablets
- The 30 mg tablets are available in pack sizes of 28, 30, 56 and 84 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

TEVA UK Limited, Eastbourne, BN22 9AG.

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