

Paroxetine 20mg and 30mg Film-coated Tablets

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.
- The full name of this medicine is paroxetine 20mg and 30mg Film-coated Tablets but within the leaflet it will be referred to as Paroxetine Tablets.

Important things you need to know about paroxetine. If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor - even if you feel anxious or worried about doing so.

You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and that you have been prescribed this medication; it might be useful to show them this leaflet.

- **Paroxetine may not start to work immediately. Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after you start treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better.**
- **Some people who are depressed may think of harming or killing themselves. If this happens you should see your doctor or go to a hospital straight away** - see section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder'.
- **If you take too many tablets it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects.**
- **Do not stop taking Paroxetine Tablets or change your dose without the advice of your doctor, even if you feel better.** If you stop taking Paroxetine Tablets abruptly you may get withdrawal reactions - see section 3 'If you stop taking Paroxetine Tablets'.
- **If you have heart problems such as fast or irregular heart rate or high blood pressure you should talk to your doctor before taking Paroxetine Tablets** - see section 2 'Warnings and precautions'.
- **Taking certain other medicines with Paroxetine Tablets may cause problems. You should tell your doctor if you are taking any other medicines** - see section 2 'Other medicines with Paroxetine Tablets'.
- **See your doctor without delay if you feel restless and feel like you can't keep still, feel 'high' or very over-excited, have jerky muscle movements which you can't control.** See section 4 - 'Possible side effects' for other important information.
- **If you are pregnant, intend to become pregnant, or are breast-feeding, you should talk to your doctor** - see section 2 'Pregnancy, breast-feeding and fertility'.
- **Paroxetine is not for use in children and adolescents under 18.**

More information on all of these points is provided in the rest of this leaflet.

What is in this leaflet:

- 1 What Paroxetine Tablets are and what they are used for
- 2 What you need to know before you take Paroxetine Tablets
- 3 How to take Paroxetine Tablets
- 4 Possible side effects
- 5 How to store Paroxetine Tablets
- 6 Contents of the pack and other information

1 What Paroxetine Tablets are and what they are used for

Paroxetine is one of a type of antidepressants known as Selective Serotonin Re-uptake Inhibitors (SSRIs). Low levels of the hormone serotonin are thought to be a cause of depression and other related conditions. Paroxetine works by bringing the levels of serotonin back to normal. Paroxetine Tablets are used in adults to treat:

- major depression
- obsessive compulsive disorder
- panic disorder with or without agoraphobia (fear of open spaces or new situations)
- social anxiety disorders/social phobias
- anxiety after traumatic experience (post-traumatic stress disorder)
- generalised anxiety disorder.

2 What you need to know before you take Paroxetine Tablets

Do not take Paroxetine Tablets if you are:

- **allergic** to paroxetine, peanut, soya or any of the other ingredients of this medicine (listed in section 6)
- taking medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride (methylene blue)) or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking Paroxetine Tablets once you have stopped taking the MAOI
- taking an **anti-psychotic** called thioridazine or pimozide.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paroxetine Tablets if you:

- are taking tamoxifen to treat breast cancer or fertility problems. Paroxetine Tablets may make tamoxifen less effective, so your doctor may recommend you take another antidepressant
- suffer from kidney, liver or heart problems
- have an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval
- have a family history of QT prolongation, heart disease such as heart failure, low heart rate, or low potassium levels or low magnesium levels
- suffer from epilepsy or have a history of fits or seizures
- have ever had episodes of mania (overactive behaviour or thoughts)
- are having electro-convulsive therapy (ECT)
- have a history of bleeding disorders, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility'), or are taking other medicines that may increase the risk of (these include medicines used to thin the blood, such as warfarin, anti-psychotics such as perphenazine or clozapine, tricyclic antidepressants, medicines used for pain and inflammation called non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam)
- suffer from diabetes
- are on a low sodium diet
- have glaucoma (increased pressure in the eye).

Children and adolescents under 18

Paroxetine should not be used for children and adolescents under 18 years. Also, patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, suicidal thoughts and anger) when they take Paroxetine Tablets. If your doctor has prescribed Paroxetine Tablets for you (or your child) 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 in you (or your child) are taking Paroxetine Tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and

behavioural development of Paroxetine Tablets in this age group have not yet been demonstrated. In studies of Paroxetine Tablets in under 18s, common side effects that affected up to 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)
- unusual bruising or bleeding (such as nose bleeds).

These studies also showed that the same symptoms affected children and adolescents taking the sugar pills (placebo) instead of Paroxetine Tablets, although these were seen less often. Some patients in these studies of under 18s had withdrawal effects when they stopped taking Paroxetine Tablets. These effects were mostly similar to those seen in adults after stopping Paroxetine Tablets (see Section 3). In addition, patients under 18 also commonly (affecting up to 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).

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 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.
- 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.

Important side effects seen with Paroxetine Tablets

Some patients who take Paroxetine Tablets develop something called akathisia, where they feel restless and feel like they can't sit or stand still. Other patients develop something called serotonin syndrome, or neuroleptic malignant syndrome, a potentially life-threatening condition where they have some or all of the following symptoms: feeling very agitated or irritable, feeling confused, feeling restless, feeling hot, sweating, shaking, shivering, hallucinations (strange visions or sounds), muscle stiffness, sudden jerks of the muscles or a fast heartbeat. The severity can increase, leading to loss of consciousness. If you notice any of these symptoms, contact your doctor. For more information on these or other side effects, see section 4.

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

Other medicines and Paroxetine Tablets

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

- monoamine oxidase inhibitors (MAOIs, including moclobemide and methylthionium chloride (methylene blue))
- medicines known to increase the risk of changes in the electrical activity of the heart (e.g. the anti-psychotics thioridazine or pimozide) - see 'Do not take Paroxetine Tablets'
- aspirin (acetylsalicylic acid), ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) like celecoxib, etodolac, diclofenac and meloxicam (used for pain and inflammation)
- tramadol and pethidine (painkillers)
- buprenorphine (to treat opioid dependence). This medicine may interact with Paroxetine Tablets and you may experience 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
- medicines called triptans, such as sumatriptan (to treat migraine)
- other antidepressants including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
- mivacurium and suxamethonium (used in anaesthesia)
- medicines such as lithium, risperidone, perphenazine, clozapine (called anti-psychotics) used to treat some psychiatric conditions
- fentanyl (used in anaesthesia or to treat chronic pain)
- a combination of fosamprenavir and ritonavir (used to treat Human Immunodeficiency Virus (HIV) infection)
- St. John's Wort (a herbal remedy for depression)
- phenobarbital, phenytoin, sodium valproate or carbamazepine (used to treat fits or epilepsy)
- atomoxetine (used to treat attention deficit hyperactivity disorder (ADHD))
- procyclidine, used to relieve tremor, especially in Parkinson's Disease
- warfarin or other medicines (called anticoagulants) used to thin the blood
- propafenone, flecainide and medicines used to treat an irregular heartbeat
- 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)
- linezolid (an antibiotic)
- tamoxifen (used to treat breast cancer or fertility problems).

Paroxetine Tablets with alcohol

Do not drink alcohol while you are taking Paroxetine Tablets. Alcohol may make your symptoms or side effects worse.

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.

Pregnancy

If you are already taking Paroxetine Tablets and have just found out that you are pregnant you should talk to your doctor **immediately**. 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 up to 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 Tablets while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Paroxetine Tablets.

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 newborn (PPHN). PPHN increases blood pressure in the blood vessels in the lungs. This may result in abnormal blood flow to the lungs and heart and the baby cannot get enough oxygen into their bloodstream.

These symptoms usually begin during the first 24 hours after birth and include: not being able to sleep or feed properly, breathing faster, blue-ish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, being very tired, 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.**

If you take Paroxetine 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 Paroxetine Tablets so they can advise you.

Breast-feeding

Paroxetine may get into breast milk in very small amounts. If you are taking Paroxetine Tablets, talk to your doctor before you start breast-feeding. You and your doctor may decide that you can breast-feed while you are taking Paroxetine Tablets.

Fertility

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

Paroxetine may cause dizziness, confusion or changes in eyesight. If you are affected by these side effects, do not drive or use machinery.

Paroxetine Tablets contain soya lecithin

If you are allergic to peanut or soya, do not take this medicinal product.

Information on sodium content

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

Paroxetine 30mg Tablets contain sunset yellow FCF (E110)

May cause allergic reactions.

3 How to take Paroxetine Tablets

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 your tablets **in the morning with food**. Swallow them **with a drink of water**. The 20mg tablets can be cut in half. **Do not chew.**

Doses

Your doctor will advise you what dose to take when you first start taking Paroxetine Tablets.

Adults

- Depression: 20mg a day to a maximum of 50mg
- Obsessive compulsive disorder: 20mg a day to a maximum of 60mg
- Panic disorder: 10mg a day to a maximum of 60mg
- Social anxiety disorder: 20mg a day to a maximum of 50mg
- Post-traumatic stress disorder: 20mg a day to a maximum of 50mg
- Generalised anxiety disorder: 20mg a day to a maximum of 50mg

Elderly

The maximum dose for people over 65 is 40mg per day.

Children and adolescents

Not recommended for use in children aged under 18 years.

Patients with liver or kidney disease

If you have trouble with your liver or kidneys, your doctor may decide that you should have a lower dose. If you have severe liver or kidney disease, the maximum dose is 20mg per day.

If you take more Paroxetine Tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Someone who has taken an overdose may have one of the symptoms listed in section 4 or the following symptoms: fever and uncontrollable tightening of the muscles.

If you forget to take Paroxetine Tablets if you forget a dose and you remember before you go to bed, take it straight away and then take the next dose at the right time. **If you only remember during the night, or the next day**, leave out the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Paroxetine Tablets

Do not stop taking Paroxetine Tablets until your doctor tells you to. When stopping treatment, your doctor will help you to reduce your dose slowly over a number of weeks or months. One way of doing this is to gradually reduce the dose of Paroxetine Tablets you take by 10mg a week. Most people find that any symptoms on stopping Paroxetine Tablets are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer.

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 Tablets, please see your doctor. They 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 Tablets.

Possible withdrawal effects when stopping treatment

Studies show that 3 in 10 patients notice one or more symptoms on stopping Paroxetine Tablets. Some withdrawal effects on stopping occur more frequently than others.

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

- feeling dizzy, unsteady or off-balance
- feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head
- some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus)
- sleep disturbances (vivid dreams, nightmares, inability to sleep)
- feeling anxious
- headaches.

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

- feeling sick (nausea)
- sweating (including night sweats)
- feeling restless or agitated
- tremor (shakiness)
- feeling confused or disorientated
- diarrhoea (loose stools)
- feeling emotional or irritable
- visual disturbances
- fluttering or pounding heartbeat (palpitations).

What to do if you are feeling no better

Paroxetine Tablets will not relieve your symptoms straight away - all antidepressants take time to work. Some people will start to feel better within a couple of weeks, but for others it may take a little longer. Some people taking antidepressants feel worse before feeling better. If you don't start to feel better after a couple of weeks, go back to your doctor who will advise you. Your doctor should ask to see you again a couple of weeks after you start treatment. Tell your doctor then if you haven't started to feel better.

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.

Stop taking this medicine and contact your doctor or go to a hospital immediately if you experience any of the following serious side effects:

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

- unusual bruising or bleeding, including vomiting blood or passing blood in your stools or urine
- not being able to pass water (urinary retention).

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

- seizures (fits)

- restlessness and feeling like you can't sit or stand still (akathisia)

- low blood sodium (causing tiredness, weakness, confusion and achy, stiff or uncoordinated muscles).

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

- **allergic reactions:** a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, itching or difficulty breathing (shortness of breath) or swallowing and feeling weak or lightheaded resulting in collapse or loss of consciousness
- skin rash, which may blister and looks like small targets, central dark spots surrounded by a paler area, with a dark ring around the edge (erythema multiforme)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome) or on much of the body surface (toxic epidermal necrolysis)
- liver problems that make the skin or whites of the eyes go yellow
- syndrome of inappropriate antidiuretic hormone production (SIADH) which is a condition in which the body develops an excess of water and a decrease in sodium (salt) concentration, as a result of improper chemical signals. Patients with SIADH may become severely ill or may have no symptoms at all
- serotonin syndrome (see section 2 'Important side effects seen with Paroxetine Tablets')
- acute glaucoma (eye pain and blurred vision).

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

- **thoughts of harming or killing yourself** while taking Paroxetine Tablets or soon after stopping treatment
- aggression
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more information.

Other side effects include:

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

- changes in sex drive or function (lack of orgasm, abnormal erection and ejaculation in men)
- feeling sick (nausea). Taking your medicine in the morning with food will reduce the chance of this happening.

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

- increase in blood cholesterol levels
- lack of appetite
- difficulty sleeping or feeling sleepy, abnormal dreams/nightmares
- dizziness, shakes (tremors), headache, difficulty concentrating, feeling agitated, yawning
- feeling unusually weak
- blurred vision
- dry mouth, diarrhoea, constipation, being sick
- weight gain
- sweating.

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

- increase or decrease in blood pressure that may make you feel dizzy or faint when you stand up suddenly
- irregular or fast heartbeat
- lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue
- abnormal dilated pupils
- skin rashes, itching
- confusion, hallucination
- an uncontrollable, involuntary passing of urine (urinary incontinence)
- if you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking Paroxetine Tablets. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.
- reduction in white blood cell count.

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

- abnormal production of breast milk in men and women
- slow heartbeat
- effects on the liver showing up in blood tests of your liver function
- panic attacks, overactive behaviour or thoughts (mania), feeling detached from yourself (depersonalisation), feeling anxious
- irresistible urge to move the legs (Restless Leg Syndrome)
- joint or muscle pain
- increase in a hormone called prolactin in the blood
- menstrual period disorders (including heavy or irregular periods, bleeding between periods and absence or delay of periods).

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

- fluid or water retention, which may cause swelling of the arms or legs
- sensitivity to sunlight
- painful erection of the penis that won't go away
- low blood platelet count.

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

- tooth grinding
- bone fractures
- ringing in the ears (tinnitus)
- inflammation of the colon (causing diarrhoea).

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 the 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 Paroxetine Tablets

Keep this medicine out of the sight and reach of children. This medicine does not require any special storage conditions. Do not take this medicine after the expiry date which is stated on the label or 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 Paroxetine Tablets contain

- The active substance (the ingredient that makes the tablet work) is paroxetine hydrochloride. Each tablet contains either 22.22mg or 33.33mg of the active ingredient (equivalent to 20mg or 30mg of paroxetine).
- The other ingredients are: Tablet core: Magnesium stearate, sodium starch glycolate (Type A), mannitol (E421), microcrystalline cellulose. Film-coating: Basic butylated methacrylate copolymer. The 20mg tablets also contain Opadry AMB white (polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), talc, lecithin soya (E322), and xanthan gum (E415)). The 30mg tablets also contain Opadry AMB blue (polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), talc, FD&C blue #2 / indigo carmine aluminium lake (E132), lecithin soya (E322), xanthan gum (E415), FD&C yellow #6 / sunset yellow FCF aluminium lake (E110) and quinoline yellow aluminium lake (E104)).

What Paroxetine Tablets look like and contents of the pack

Paroxetine 20mg Tablets are white to off-white, round, biconvex, bevel edged film-coated tablets, diameter 10 mm, marked with "KP" and "2" on either side of a breakline on one side and a breakline on the other side with side score.

Paroxetine 30mg Tablets are light blue to blue, round, biconvex, bevel edged film-coated tablets, diameter 12 mm, marked with "KP3" on one side and a breakline on the other side.

Pack sizes are 30 tablets.

Marketing Authorisation Holder and Manufacturer

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Manufacturer

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