

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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# PAROXAL

20mg Film-coated Tablets

## PAROXETINE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 •*

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### What is in this leaflet?

1. What PAROXAL is and what it is used for
2. Before you take PAROXAL
3. How to take PAROXAL
4. Possible side effects
5. How to store PAROXAL

#### 1. WHAT PAROXAL IS AND WHAT IS IT 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 is used in adults to treat:

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

#### 2. BEFORE YOU TAKE PAROXAL

##### **Do not take PAROXAL tablets and tell your doctor if you are:**

- **allergic** (hypersensitive) to paroxetine or any of the other ingredients of this medicine
- taking medicines called **pimozide** or **monoamine oxidase inhibitors** (MAOIs, including moclobemide), or have taken them at any time within the last two weeks

- taking a **tranquilliser** called thioridazine.

**PAROXAL tablets contains soya lecithin**

If you are allergic to peanut or soya, do not use this medicine.

***Talk to your doctor, pharmacist or nurse before taking PAROXAL tablets if you:***

- suffer from **eye, kidney, liver or heart** problems
- suffer from **epilepsy** or have a **history of fits**
- have episodes of **mania** (overactive behaviour or thoughts)
- are having electro-convulsive therapy (**ECT**)
- have a **history of bleeding disorders**
- suffer from **diabetes**
- are on a **low sodium diet**
- have **glaucoma** (excess pressure in the eye).

***Take special care with Paroxetine***

Contact your doctor if you develop symptoms such as confusion, restlessness, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat, since these symptoms could be a sign of “serotonin syndrome”.

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.**

***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, oppositional behaviour and anger) 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. You should inform your doctor if any of the symptoms listed above develop or worsen when you (or your child) are taking Paroxetine. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Paroxetine in this age group have not yet been demonstrated. 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) and unusual bruising or bleeding (such as nose bleeds). 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 (see Section 3, How to take, inside this leaflet). In addition, patients under 18 also commonly (affecting 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).

**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 PAROXAL tablets

***Please tell your doctor or pharmacist:***

if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Especially:

- monoamine oxidase inhibitors (MAOIs, including moclobemide), or have taken them at any time within the last two weeks
- thioridazine (a tranquilliser)
- fentanyl or pethidine (for severe pain)
- tramadol (a painkiller)
- medicines called triptans, such as sumatriptan (to treat migraine)
- other antidepressants including other Selective Serotonin Reuptake Inhibitors (SSRIs)
- drugs to treat some psychiatric conditions such as lithium, perphenazine
- St John's Wort, (a herbal remedy for depression)
- linezolid (an antibiotic)
- methylene blue (used to treat high levels of methaemoglobin in the blood).

Concomitant use of above-mentioned medicinal products may lead to 'serotonin syndrome' (see "Take special care with paroxetine").

Other drugs taken with Paroxetine that may cause unwanted effects include:

- aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) such as celecoxib, etodolac, meloxicam and refecoxib (for pain and inflammation)
- other antidepressants including, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
- drugs to treat some psychiatric conditions such as clozapine, risperidone, pimozide
- sodium valproate, phenobarbital, phenytoin or carbamazepine (to treat epilepsy)
- atomoxetine (to treat attention deficit hyperactivity disorder (ADHD))
- procyclidine (to relieve tremor, especially in Parkinson's Disease)
- warfarin or other anticoagulants (to thin the blood)
- propafenone, flecainide (to treat an irregular heartbeat)
- tamoxifen (used in breast cancer)
- fosamprenavir/ritonavir (used in HIV)
- metoprolol (for high blood pressure and heart problems)
- rifampicin (to treat tuberculosis (TB) and leprosy).
- Pravastatin (used to treat high cholesterol)
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***Pregnancy, breast-feeding and fertility***

If you are planning to become pregnant or are breast-feeding ask your doctor, midwife or pharmacist for advice before taking this medicine. If you are already taking Paroxetine 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 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.

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, 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.**

Medicines like Paroxetine may reduce the quality of your sperm. Although the impact of this on fertility is unknown, fertility may be affected in some men whilst taking Paroxetine.

### ***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.

### ***PAROXAL tablets with Alcohol***

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

## ***3. HOW TO TAKE PAROXAL***

Always take paroxetine exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Take your tablets **in the morning with food**.

Swallow them **with a drink of water**.

The tablets can be broken into halves.

**Do not chew.**

**Doses:**

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

- **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
  - 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 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. Signs of overdose include being sick, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety and rapid heart beat.

### ***If you forget to take the tablets***

Do not take a double dose to make up for a forgotten dose. **If you do forget a dose, and you remember before you go to bed**, take it straight away, 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.

### ***If you stop taking the tablets***

**Do not stop** treatment early because your doctor will help you to reduce your dose slowly over a number of weeks or months. This should help reduce the chance of withdrawal effects such as dizziness or a feeling of unsteadiness, tingling, electric shock sensations, burning sensations, sleep disturbances, intense dreams, restlessness, anxiety, feeling sick, shaking, confusion, sweating, headache, diarrhoea, irregular heartbeat, emotional instability, irritability or changes in vision. **Talk to your doctor** before you stop taking the tablets and follow their advice.

### **What to do if you're feeling no better**

Paroxetine 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.

### **4. POSSIBLE SIDE EFFECTS**

As with other medicines paroxetine can cause side effects, but not everybody gets them.

Contact your doctor at once if you experience any of the following:

- an allergic reaction: red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, itching or difficulty breathing or swallowing and feel weak or light headed resulting in collapse or loss of consciousness
- unusual bruising or bleeding, including vomiting blood or passing blood in your stools
- not being able to pass water
- seizures (fits)
- akathisia (restlessness, and feeling like you can't sit or stand still),
- low blood sodium (causing tiredness, weakness, confusion and achy, stiff or uncoordinated muscles)
- serotonin syndrome (agitation, confusion, restlessness, sweating, exaggerated reflexes, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat.
- Severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), Severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), Widespread skin rash – circular, irregular red patches on the skin of the hands and arms (Erythema multiforme)

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- **Very common** (occurs in more than 1 in 10 users):
  - changes in sex drive or function (lack of orgasm, abnormal erection and ejaculation in men).
  - impaired concentration
  - feeling sick
- **Common** (occurs in less than 1 in 10 users):
  - dry mouth, diarrhoea, constipation, being sick
  - lack of appetite, weight gain, increase in blood cholesterol levels
  - difficulty sleeping, abnormal dreams/nightmares, feeling sleepy, dizziness, headache
  - shakes (tremors), feeling agitated
  - weakness or loss of strength
  - sweating
  - blurred vision, yawning.
- **Uncommon** (occurs in less than 1 in 100 users):
  - increase or decrease in blood pressure
  - irregular or fast heartbeat
  - lack of movement, stiffness, shaking
  - abnormal movements of the mouth and tongue
  - abnormal dilated pupils
  - skin rash, itching
  - difficulty passing water, bladder weakness or increase in the need to pass urine
  - if you are a diabetic patient you may notice a loss of control of your blood sugar levels
- **Rare** (occurs in less than 1 in 1,000 users):
  - abnormal production of breast milk in men and women
  - high levels of prolactin in the blood
  - slow heartbeat
  - effects on the liver showing up in liver function tests
  - panic attacks, overactive behaviour or thoughts (mania), feeling detached from yourself (depersonalisation), feeling anxious, restless leg syndrome (RLS)

- joint or muscle pain.
- **Very rare** (occurs in less than 1 in 10,000 users):
  - reduction in platelets in the blood (as seen in blood tests)
  - yellowing of the skin or whites of the eyes
  - fluid or water retention which may cause swelling of the arms or legs
  - sensitivity to sunlight
  - acute glaucoma (eye pain and blurred vision)
  - bleeding in the stomach
  - painful erection of the penis that won't go away.
- **Other possible side effects** (frequency cannot be estimated from the data):
  - bone fractures, ringing in the ears, suicidal ideation and suicidal behaviour (see section 2), aggression.

### ***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.

By reporting side effects you can help provide more information on the safety of this medicine.

### ***5. HOW TO STORE PAROXAL***

Keep out of the sight and reach of children.

No special precautions for storage.

Do not use Paroxetine after the expiry date stated on the label. The expiry date refers to the last day of that month.

Ask your pharmacist how to dispose of medicines no longer required.