



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Paroxetine 10 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 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 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 is a treatment for adults with depression and/or anxiety disorders.** The anxiety disorders that Paroxetine is used to treat are: obsessive compulsive disorder (repetitive, obsessive thoughts with uncontrollable behaviour), panic disorder (panic attacks, including those caused by agoraphobia, which is a fear of open spaces), social anxiety disorder (fear or avoidance of social situations), post traumatic stress disorder (anxiety caused by a traumatic event) and generalised anxiety disorder (generally feeling very anxious or nervous).

Paroxetine is one of a group of medicines called SSRIs (selective serotonin reuptake inhibitors).

Everyone has a substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not fully understood how Paroxetine and other SSRIs work but they may help by increasing the level of serotonin in the brain. Treating depression or anxiety disorders properly is important to help you get better.

#### 2. What you need to know before you take Paroxetine

##### Do not take Paroxetine

- **If you are 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 once you have stopped taking the MAOI.
- **If you are taking an anti-psychotic** called thioridazine or an anti-psychotic called pimozide.
- **If you are allergic** to paroxetine or any of the other ingredients of this medicine (listed in section 6).

**If any of these apply to you**, tell your doctor before taking Paroxetine.

##### Warnings and precautions

##### Talk to your doctor or pharmacist before taking Paroxetine

- Are you taking any other medicines (see *Other medicines and Paroxetine*, inside this leaflet)?
- Are you taking tamoxifen to treat breast cancer or fertility problems? Paroxetine may make tamoxifen less effective, so your doctor may recommend you take another antidepressant.
- Do you have kidney, liver or heart trouble?
- Do you have epilepsy or have a history of fits or seizures?
- Have you ever had episodes of mania (overactive behaviour or thoughts)?
- Are you having electro-convulsive therapy (ECT)?
- Do you have a history of bleeding disorders, or are you taking other medicines that may increase the risk of bleeding (these include medicines used to thin the blood, such as warfarin, antipsychotics such as perphenazine or clozapine, tricyclic antidepressants, medicines used for pain and inflammation called non-steroidal anti-inflammatory drugs or NSAIDs, such as acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam)?
- Do you have diabetes?
- Are you on a low sodium diet?
- Do you have glaucoma (pressure in the eye)?
- Are you pregnant or planning to get pregnant (see *Pregnancy, breast-feeding and fertility*, inside this leaflet)?
- Are you under 18 years old (see *Children and adolescents*, inside this leaflet)?

**If you answer YES to any of these questions**, and you have not already discussed them with your doctor, **go back to your doctor and ask what to do about taking Paroxetine.**

##### Children and adolescents

**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 Paroxetine*, 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).

##### 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 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.

##### Important side effects seen with Paroxetine

Some patients who take Paroxetine 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**, 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 of Paroxetine, see section 4, *Possible Side Effects*, inside this leaflet.

##### Other medicines and Paroxetine

Some medicines can affect the way Paroxetine works, or make it more likely that you will have side effects. Paroxetine can also affect the way some other medicines work. These include:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide and methylthionium chloride (methylene blue)) – see *Do not take Paroxetine*, inside this leaflet.
- Thioridazine or pimozide, which are **anti-psychotics** – see *Do not take Paroxetine*, inside this leaflet.
- 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**.
- Medicines called triptans, such as sumatriptan, used to treat **migraine**.
- Other **antidepressants** including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine, nortriptyline and desipramine.
- A **dietary supplement** called tryptophan.
- 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, which is 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 which is 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, which is used to **treat breast cancer or fertility problems**.

**If you are taking or have recently taken any of the medicines in this list**, and you have not already discussed these with your doctor, **go back to your doctor and ask what to do**. The dose may need to be changed or you may need to be given another medicine.

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

##### Taking Paroxetine with food, drink and alcohol

Do NOT drink alcohol while you are taking Paroxetine. Alcohol may make your symptoms or side effects worse. Taking Paroxetine in the morning with food will reduce the likelihood of you feeling sick (nausea).

##### 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 for advice** before taking this medicine. In babies whose mothers took Paroxetine during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to up to 2 in 100 babies in mothers who took Paroxetine. You and your doctor may decide that it is better for you to change to another treatment or 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.

**Make sure your midwife or doctor knows you are taking Paroxetine.** When taken during pregnancy, particularly late pregnancy, medicines like Paroxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN). In PPHN, the blood pressure in the blood vessels between the baby's heart and the lungs is too high. If you take Paroxetine during the last 3 months of pregnancy, your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth.

Symptoms include:

- trouble with breathing;
- a blue-ish skin or being too hot or cold;
- blue lips;
- vomiting or not feeding properly;
- being very tired, not able to sleep or crying a lot;
- stiff or floppy muscles;
- tremors, jitters or fits;
- exaggerated reflexes.

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, **contact your doctor or midwife who will be able to advise you.**

**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 breast-feeding. You and your doctor may decide that you can breast-feed while you are taking Paroxetine.

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

Possible side effects of Paroxetine include dizziness, confusion, feeling sleepy or blurred vision. If you do get these side effects, do NOT drive or use machinery.

#### 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.

Sometimes you may need to take more than one tablet.

The usual doses for different conditions are set out in the table below.

	Starting dose	Recommended daily dose	Maximum daily dose
Depression	20 mg	20 mg	50 mg
Obsessive Compulsive Disorder (obsessions and compulsions)	20 mg	40 mg	60 mg
Panic Disorder (panic attacks)	10 mg	40 mg	60 mg
Social Anxiety Disorder (fear or avoidance of social situations)	20 mg	20 mg	50 mg
Post Traumatic Stress Disorder	20 mg	20 mg	50 mg
Generalised Anxiety Disorder	20 mg	20 mg	50 mg

**Your doctor will advise you what dose to take when you first start taking Paroxetine.** Most people start to feel better after a couple of weeks. If you do NOT start to feel better after this time, talk to your doctor, who will advise you. He or she may decide to increase the dose gradually, 10 mg at a time, up to a maximum daily dose.

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

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

##### Do NOT chew.

Your doctor will talk to you about how long you will need to keep taking your tablets. This may be for many months or even longer.

##### Older people

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

##### 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 of Paroxetine than usual.

If you have severe liver or kidney disease the maximum dose is 20 mg per day.

#### **If you take more Paroxetine than you should**

**Never take more tablets than your doctor recommends.** If you take too many Paroxetine tablets (or someone else does), tell your doctor or a hospital straight away. Show them the pack of tablets.

Someone who has taken an overdose of Paroxetine may have any one of the symptoms listed in section 4, *Possible side effects*, or the following symptoms: fever, uncontrollable tightening of the muscles.

#### **If you forget to take Paroxetine**

Take your medicine at the same time every day.

**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.

#### **What to do if you are not feeling 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 do not 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 first start treatment. Tell your doctor if you have not started to feel better.

#### **If you stop taking Paroxetine**

**Do NOT stop taking Paroxetine until your doctor tells you to.**

**When stopping Paroxetine,** 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. One way of doing this is to gradually reduce the dose of Paroxetine you take by 10 mg a week. Most people find that any symptoms on stopping Paroxetine 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, please see your doctor. He or she 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**

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

#### **Common side effects, likely to 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) when they take Paroxetine.
- Sleep disturbances (vivid dreams, nightmares, inability to sleep).
- Feeling anxious.
- Headaches.

#### **Uncommon side effects, likely to affect up to 1 in every 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).

**Please see your doctor if you are worried about withdrawal effects when stopping Paroxetine.**

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. Side effects are more likely to happen in the first few weeks of taking Paroxetine.

#### **See the doctor if you get any of the following side effects during treatment.**

You may need to contact your doctor or go to a hospital straight away.

#### **Uncommon side effects, likely to affect up to 1 in every 100 people:**

- **If you have unusual bruising or bleeding,** including vomiting blood or passing blood in your stools, **contact your doctor or go to a hospital straight away.**
- **If you find that you are not able to pass water, contact your doctor or go to a hospital straight away.**

#### **Rare side effects, likely to affect up to 1 in every 1,000 people:**

- **If you experience seizures (fits), contact your doctor or go to a hospital straight away.**
- **If you feel restless and feel like you cannot sit or stand still,** you may have something called akathisia. Increasing your dose of Paroxetine may make these feelings worse. If you feel like this, **contact your doctor.**
- **If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles** this may be because your blood is low in sodium. If you have these symptoms, **contact your doctor.**

#### **Very rare side effects, likely to affect up to 1 in every 10,000 people:**

- **Allergic reactions, which may be severe to Paroxetine.**  
If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to itch or have difficulty breathing (shortness of breath) or swallowing and feel weak or lightheaded resulting in collapse or loss of consciousness, **contact your doctor or go to a hospital straight away.**  
**If you have some or all of the following symptoms** you may have something called **serotonin syndrome.** The symptoms include: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat. If you feel like this **contact your doctor.**
- **Acute glaucoma.**  
If your eyes become painful and you develop blurred vision, **contact your doctor.**

#### **Frequency unknown**

- Some people have had thoughts of harming or killing themselves while taking Paroxetine or soon after stopping treatment (see section 2).
- Some people have experienced **aggression** while taking Paroxetine.

#### **Other possible side effects during treatment**

#### **Very common side effects, likely to affect more than 1 in 10 people:**

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

#### **Common side effects, likely to affect up to 1 in 10 people:**

- Increases in the level of cholesterol in the blood.
- Lack of appetite.
- Not sleeping well (insomnia) or feeling sleepy.
- Abnormal dreams (including nightmares).
- Feeling dizzy or shaky (tremors).
- Headache.
- Difficulty in concentrating.
- Feeling agitated.
- Feeling unusually weak.

- Blurred vision.
- Yawning, dry mouth.
- Diarrhoea or constipation.
- Vomiting.
- Weight gain.
- Sweating.

#### **Uncommon side effects, likely to affect up to 1 in every 100 people:**

- A brief increase in blood pressure, or a brief decrease that may make you feel dizzy or faint when you stand up suddenly.
- A faster than normal heartbeat.
- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue.
- Dilated pupils.
- Skin rashes.
- Itching.
- Feeling confused.
- Having hallucinations (strange visions or sounds).
- An inability to urinate (urinary retention) or 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. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.

#### **Rare side effects, likely to affect up to 1 in every 1000 people:**

- Abnormal production of breast milk in men and women.
- A 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 Legs Syndrome).
- Pain in the joints or muscles.
- 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 side effects, likely to affect up to 1 in every 10,000 people:**

- 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) called erythema multiforme.
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome).
- A widespread rash with blisters and skin peeling 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.
- 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.

Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take Paroxetine.

An increased risk of bone fractures has been observed in patients taking this type of medicines.

#### **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 (website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)).

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.**

Do not use this medicine after the expiry date which is stated on the blister and the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

If you are using half tablets, be careful to keep them safely in the pack.

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 (10 mg), as the hydrochloride hemihydrate.

The other ingredients are

*Tablet core:*

Calcium hydrogen phosphate dihydrate (E341)

Starch, pregelatinized

Sodium starch glycolate (Type A)

Magnesium stearate (E470b)

*Tablet coating:*

Hypromellose (E464)

Titanium dioxide (E171)

Macrogol 400

Polysorbate 80 (E433)

#### **What Paroxetine looks like and contents of the pack**

Paroxetine 10 mg film-coated tablets are white, modified capsule shaped, film-coated tablets of approximately 8,90 mm length and 4,90 mm width, scored on one side and debossed with '457' on the other side.

The tablets are provided in pack sizes of 20, 28, 30, 50, 60 and 100 tablets.

Not all packs may be available.

#### **Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder*

Amneal Pharma Europe Limited

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**This leaflet was last revised in December 2017**