

## **Paroxetine Hydrochloride Tablets 20mg USP Taj Pharma**

(Paroxetine)

**Package leaflet: Information for the patient  
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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 (major depressive episode) 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 belongs to 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 allergic to paroxetine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide, linezolid 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 anti-psychotic medicines called thioridazine or pimozone.

**If any of these apply to you, tell your doctor and do not take Paroxetine.**

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking paroxetine

- if you have problems with your kidneys or liver or if you have heart trouble
- if you have epilepsy or have a history of fits or seizures
- if you have ever had episodes of mania (overactive behaviour or thoughts)

- if you are having a treatment for severe depression called electro convulsive therapy (ECT)
- if you are diabetic
- if you have low levels of sodium in your blood
- if you have glaucoma (high pressure in the eye)
- if you are taking tamoxifen to treat breast cancer or fertility problems. Paroxetine may make tamoxifen less effective, so your doctor may recommend you take another antidepressant
- if 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, such as clomipramine, medicines used for pain and inflammation called non-steroidal anti-inflammatory drugs or NSAIDs, such as acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam)
- if you under 18 years old (see ‘Children and adolescents under 18’).

**Please check with your doctor if any of the above apply to you or you are not sure.**

### **Children and adolescents under 18**

**Paroxetine film-coated tablets should not be used for children and adolescents under 18 years.** 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. Despite this, your doctor may prescribe paroxetine for patients under 18 because he/she decides that this is in their best interests. 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 conditions 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 this age group have not yet been demonstrated.

In studies in children under 18 years old some patients 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’).

### **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.

Please discuss these things with your doctor if you have any concerns.

### **Important side effects seen with Paroxetine film-coated tablets**

Some patients who take paroxetine develop akathisia, where they **feel restless and feel like they can't sit or stand still**. Other patients develop **serotonin syndrome**, where they have

some or all of the following symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat. 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'.

### Other medicines and Paroxetine

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

Some medicines can affect the way paroxetine works, or make it more likely that you'll have side effects. Paroxetine can also affect the way some other medicines work.

These include:

- Medicines called **monoamine oxidase inhibitors** (MAOIs, including moclobemide to treat depression and methylthioninium chloride (methylene blue)) see 'Do not take paroxetine', in this section
- Thioridazine or pimozide (which are **anti-psychotics**, used to treat psychiatric conditions) see 'Do not take Paroxetine', in this section
- Aspirin (acetylsalicylic acid), ibuprofen or other medicines called non-steroidal anti-inflammatory drugs (NSAIDs) like celecoxib or rofecoxib, etodolac, diclofenac and meloxicam (used to treat **pain and inflammation**)
- Medicines used to reduce the risk of blood clots forming (antiplatelets) such as clopidogrel
- Pain killers e.g. tramadol, pethidine
- Medicines called triptans e.g. sumatriptan (used to treat **migraine**)
- Other medicines to treat depression including other SSRIs and tricyclic antidepressants such as clomipramine, nortriptyline and desipramine
- A **dietary supplement** called tryptophan
- Medicines such as lithium, risperidone, perphenazine, clozapine (called anti-psychotics)

- Fentanyl, which is used in general **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 or carbamazepine (used to treat **fits or epilepsy**)
- Atomoxetine (to treat **attention deficit hyperactivity disorder (ADHD)**)
- Procyclidine (to relieve tremor, especially in **Parkinson's Disease**)
- Warfarin or other medicines (called anticoagulants) used to **thin the blood**
- Medicines used to treat an **irregular heartbeat** such as propafenone and flecainide
- Metoprolol, a beta-blocker (to treat **high blood pressure and heart problems**)
- Pravastatin, used to treat **high cholesterol**
- Rifampicin (to treat **tuberculosis (TB) and leprosy**)
- Linezolid (an **antibiotic** used to treat infection)
- Tamoxifen, which is used to treat **breast cancer or fertility problems**
- Mivacurium or suxamethonium (medicines used to relax muscles)

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

### Paroxetine with food 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 might be pregnant or are planning to have a baby, **ask your doctor or pharmacist for advice before taking this medicine**. Paroxetine is not recommended during pregnancy as it may cause harm to the baby. 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 and/or doctor know you are 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), 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.**

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 pass into breast milk in very small amounts.** If you are taking paroxetine, talk to your doctor before you start breast-feeding.

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.

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

	<b>Starting dose</b>	<b>Recommended daily dose</b>	<b>Maximum daily dose</b>
Depression	20 mg	20 mg	50 mg
Obsessive Compulsive Disorder	20 mg	40 mg	60 mg
Panic Disorder	10 mg	40 mg	60 mg
Social Anxiety Disorder	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 film -coated tablets.** Most people start to feel better after a couple of weeks. If you don't 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. Do not chew the tablets but swallow them whole with a drink of water.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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.

**Use in older people**

If you are elderly (over 65) the maximum dose you should take is 40 mg per day.

**Use in children and adolescents**

**Children and adolescents under 18 years old** should not usually take paroxetine, unless your doctor has decided that taking this medicine is in their best interest.

**Patients with liver or kidney disease**

If you have trouble with your liver or severe kidney disease, your doctor may decide that you should have a lower dose of paroxetine than usual.

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

Never take more tablets than your doctor recommends. If you take too many tablets (or someone else does), tell your doctor or go to 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: being sick, widening of the pupils, fever, headache, uncontrollable tightening of the muscles and increase in heart rate.

**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'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. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't 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 then 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** (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, and 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).

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 product, 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.

**If any of the following happen tell your doctor immediately or go to your nearest hospital emergency department:**

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

- Unusual bruising or bleeding, including vomiting blood or passing blood in your stools
- Being unable to pass water.

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

- Seizures (fits)

- Restlessness and you feel like you can't sit or stand still, you may have a serious condition called akathisia. Increasing your dose of paroxetine may make these feelings worse.

**Tiredness, feeling weak or confused and have achy, stiff or uncoordinated muscles** this may be because your blood is low in sodium.

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

- Allergic reactions, which may be severe  
 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
- 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)
- 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
- If you have some or all of the following symptoms you may have a serious condition called serotonin syndrome: feel confused, restless, and suffer from sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat
- Your eyes become painful and you develop blurred vision. This may be a sign of glaucoma

- Your skin or whites of your eyes go yellow, which may be a sign of liver problems.

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

- Have thoughts of harming or killing yourself. Suicidal behaviour has been reported during paroxetine therapy or early after treatment discontinuation.

**Other possible side effects during treatment**

**Very common** (may 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** (may affect up to 1 in 10 people)

- Decreased appetite
- Not sleeping well (insomnia) or feeling sleepy
- Abnormal dreams (including nightmares)
- Feeling dizzy or shaky (tremors)
  - Headache
- Feeling agitated
- Feeling unusually weak
- Yawning, dry mouth
- Diarrhoea or constipation
- Weight gain
- Sweating
- Increases in cholesterol levels
- Being sick (vomiting)
- Unable to concentrate properly.

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

- A faster than normal heartbeat
- A brief increase in blood pressure, or a brief decrease in blood pressure that may make you feel dizzy or faint when you stand up suddenly
- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue
- Dilated pupils

- 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** (may affect up to 1 in 1,000 people)

- Abnormal production of breast milk in men and women
- A slow heartbeat
- An increase of liver enzymes which can be seen in a blood test
- Panic attacks
- Overactive behaviour or thoughts (mania)
- Feeling detached from yourself (depersonalisation)
- Feeling anxious
- Pain in the joints or muscles
- Irresistible urge to move the legs (Restless legs syndrome)
- 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
  - Unexplained or unusual bleeding or bruising. These may be signs of having a low blood platelet count.

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

- Aggression
- Buzzing, hissing, whistling, ringing or persistent noise in the ears (Tinnitus).

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

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.

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).

#### **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.

### **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 (EXP) which is stated on the bottle, blister or carton.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light.

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 film-coated tablets contain

The active substance is paroxetine.

Each film coated tablet contains:

Paroxetine Hydrochloride USP  
Equivalent to Paroxetine 20mg  
Excipients q.s.

Colours: Indigo Carmine Lake & Titanium Dioxide BP

The other ingredients are:

Tablet core: Calcium hydrogen phosphate, colloidal anhydrous silica, sodium starch glycolate and magnesium stearate.

Tablet coat: Talc, titanium dioxide, and basic butylated methacrylate copolymer.

#### **Contents of the pack**

Blisters packs containing 7, 14, 28, 30, 50, 100 and 500 tablets.

Not all pack sizes may be marketed.

#### **7. Manufactured In India By:**

**TAJ PHARMACEUTICALS LTD.**

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