Paroxetine 20 mg Tablets
Paroxetine 30 mg 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.

SANDOZ

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 methylthioninium 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 antipsychotic 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 without 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, anti-psychotics 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)?
- Are you pregnant or planning to get pregnant (see Pregnancy, breast-feeding and fertility, inside this leaflet)?
- Do you have diabetes?
- Are you on a low sodium diet?
- Do you have glaucoma (pressure in the eye)?
- Are you under 18 years old (see Children and adolescents under 18, 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 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 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 nosebleeds). 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.

Medicines like Paroxetine (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
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 and methylthioninium 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
- 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, buprenorphine and pethidine, **painkillers**
- **Buprenorphine combined with naloxone, substitution treatment for opioid drug addiction.**
- 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.

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
Pregnancy:
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.

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 about 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**.

If you take Paroxetine 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 so they can advise you.

Breast-feeding:
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.

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
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.

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

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 or half a tablet.
The recommended 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 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.

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Take your tablets in the morning with food.
Swallow them with a drink of water. Do not chew.
20 and 30 mg film-coated tablets can be divided into equal doses if required

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.

Elderly
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 take more Paroxetine than you should
Never take more tablets than your doctor recommends. If you take too many Paroxetine (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'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 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 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 (may effect 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 (may effect 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 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 (may affect up to 1 in 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 (may affect up to 1 in 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 can't 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 (may affect up to 1 in 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 or neuroleptic malignant syndrome.** The symptoms include: 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 feel like this **contact your doctor.**
- **Acute glaucoma.**

If your eyes become painful and you develop blurred vision, **contact your doctor.**

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

If you experience these side effects, contact your doctor.

Other possible side effects during treatment

Very common side effects (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 side effects (may 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 (may affect up to 1 in 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).
- Reduction in white blood cell count
- 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 dose of your insulin or diabetes medicines.

Rare side effects (may affect up to 1 in 1,000 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 (may affect up to 1 in 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.

Not known (frequency cannot be estimated from the available data)
- Tooth grinding
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus)
- Inflammation of the colon (causing diarrhoea)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information

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

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

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 carton and blister or bottle after EXP.

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

Blister (Al/PVC):
For 30 mg: Do not store above 30 °C.

For 20 mg: This medicinal product does not require any special storage conditions.

HDPE bottle:
For 20 mg and 30 mg: Do not store above 30 °C.

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 20 mg & 30 mg contains
The active substance is paroxetine (as hydrochloride)
Paroxetine 20 mg film-coated tablets
Each film-coated tablet contains 20 mg paroxetine (as hydrochloride).

Paroxetine 30 mg film-coated tablets
Each film-coated tablet contains 30 mg paroxetine (as hydrochloride).

The other ingredients are:
Tablet core
Mannitol
Cellulose, microcrystalline
Copovidone K28
Sodium starch glycollate (type A)
Silica, colloidal anhydrous
Magnesium stearate

Tablet-coating
Hypromellose 5 cps
Talc Titanium dioxide (E 171)
Additionally for 30 mg film-coated tablets only:
Ferric oxide red (E 172)
Indigo carmine aluminium lake (E 132)

What Paroxetine looks like and contents of the pack
20 mg film-coated tablets:
White, round bisected film-coated tablet with a pressure sensitive score notch, encoded "PX 20".

30 mg film-coated tablets:
Blue, oval, convex film-coated tablet with a pressure sensitive score, encoded "PX 30".

The film-coated tablets are packed in PVC/ALU blisters and inserted in a carton or packed in a HDPE bottle with a LDPE screw cap.

Pack sizes:
20 mg: 7, 10, 14, 15, 20, 28, 30, 40, 50, 50x1, 60, 100, 200 and 250 film-coated tablets
30 mg: 7, 10, 14, 20, 28, 30, 50, 60, 100 and 250 film-coated tablets

Not all pack sizes may be marketed.

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