



Package leaflet: Information for the user

Paroxetine 20 mg film-coated tablets Paroxetine 30 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:

- What Paroxetine is and what it is used for
- What you need to know before you take Paroxetine
- 3. How to take Paroxetine Possible side effects
- How to store Paroxetine
- 6 Contents of the pack and other information

1. What Paroxetine is and what it is used for

Serotonin Reuptake Inhibitors (SSRIs), which are antidepressants. Paroxetine is used in the treatment of:

Paroxetine belongs to a group of medicines called Selective

Depression (major depressive episodes).

- Obsessive Compulsive Disorder (compulsive thoughts and compulsive actions) (OCD).
- Panic disorder with and without agoraphobia (e.g. fear of leaving the house, entering shops, or fear of public places). Social phobia (overwhelming fear or avoidance of everyday
- social situations). Generalized anxiety disorder (more permanent present fear, in
- which cronic nervous worring is prominent). Post-traumatic stress disorder(anxiety caused by a traumatic

2. What you need to know before you 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 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.
- concomitant use of paroxetine with thioridazine or pimozide (medicines for psychoses) is contraindicated.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paroxetine Use in children and adolescents under 18 years of age: Paroxetine should normally not be used for children and adolescents under 18 years. Also you should know that 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 a patient under 18 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 patients under 18 are taking Paroxetine. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioral 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

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. if you develop symptoms such as inner sense of restlessness

- and psychomotor agitation such as an inability to sit or stand still usually associated with subjective distress (akathisia). This is most likely to occur within the first few weeks of treatment. Increasing the dose of Paroxetine may make these feelings worse (see section "Possible side effects"). if you develop symptoms such as feeling confused, feeling
- restless, 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 so called "serotonin syndrome". if you have a history of mania (overactive behaviour or
- thoughts). If you are entering a manic phase, you should stop taking Paroxetine. Ask your doctor for advice. if you have heart, liver or kidney problems. In patients with severe renal impairment or those with hepatic impairment a
- dose reduction is recommended. if you have diabetes. Paroxetine can raise or lower your blood sugar. The dose of your insulin or anti-diabetes medicine taken
- orally may need to be adjusted. if you have epilepsy. if you develop seizures during treatment with Paroxetine, you
- should contact your doctor.
- if your treatment for depression is electro convulsive therapy
- if you have glaucoma (elevated pressure in your eyes).
- if you are at a risk of a decreased sodium level in the blood (hyponatraemia), e.g. from concomitant medications and
- cirrhosis. Hyponatraemia has been reported rarely during treatment with Paroxetine, predominantly in the elderly. if you have or have had a blood disorder, (e.g. abnormal bleeding in the skin or in the stomach).
- if you use medicines which possibly increase the tendency to bleed (these include medicines used to thin the blood, such as
- warfarin, antipsychotics such as perphenazine or or tricyclic antidepressants, medicines used for pain and or clozapine, inflammation called non steroidal anti inflammatory drugs or NSAIDs, such as acetylsalicylic acid, ibuprofen, celecoxib, etodolac, diclofenac, meloxicam) 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

Please consult your doctor, even if these statements were applicable to you at any time in the past.

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

Other medicines and Paroxetine

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 and methylthioninium chloride (methylene blue) —see Do not take Paroxetine, inside this
- 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 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, and tricyclic antidepressants like clomipramine, nortriptyline and desipramine
- A dietary supplement called tryptophan Medicines such as lithium, risperidone, perphenazine and
- 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 carbamazapine,
- 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 heart beat 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 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.

If you are taking any other medicines, including ones you have bought yourself, check with your doctor or pharmacist before taking Paroxetine. They will know if it is safe for you to do so.

Paroxetine with food and drink and alcohol

Food: The tablets should be taken in the morning with food. This will reduce the likelihood of you feeling sick (nausea). Alcohol: Do not drink alcohol while you are taking Paroxetine. Alcohol may take your symptoms or side effect

Pregnancy and, breast-feeding and fertility

Talk to your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mother 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 to 2 in 100 babies in mothers who took paroxetine. 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.

Make sure your midwife or doctor know you're 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 breather faster and appear bluish These symptoms usually begin during the first 24 hours after the baby is born. Symptoms include:

- trouble 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

If these happens to your baby you should contact your midwife and/or doctor immediately.

Breast-feeding: Paroxetine may pass 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**

Paroxetine may cause side-effects (such as dizziness, confusion,

feeling sleepy, or blurred vision) that affect how well you concentrate and how quickly you can react. If you get these side effects, do not drive or operate machines, or do anything else where you need to be alert and concentrate. Paroxetine contains lactose

Paroxetine contains small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Paroxetine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablet or tablet halves should be swallowed rather than

Drink a glass of water with your medicine, preferably in the morning

chewed.

The recommended dose is: **Adults**

Depression The recommended dose is 20 mg daily. Depending on your

response, the dose may be increased gradually to 50 mg daily in 10 mg steps. In general, improvement in patients starts after one week but may

only become evident from the second week of therapy. The treatment should be continued for at least 6 months. Obsessive thoughts and obsessive actions (OCD) The initial dose is 20 mg daily. Depending on your response, the

dose may be increased gradually to 40 mg daily in 10 mg steps. The recommended dose is 40 mg daily. The maximum dose is

60 mg daily. The treatment should be continued for several months. Panic disorder The initial dose is 10 mg daily. Depending on your response, the dose may be gradually increased to 40 mg daily in 10 mg steps. The recommended dose is 40 mg daily. The maximum dose is

60 mg daily. The treatment should be continued for several months.

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Social phobia, generalized anxiety disorder and post-traumatic stress disorder

The recommended dose is 20 mg daily. Depending on your response, the dose may be increased gradually to 50 mg in 10 mg steps. The maximum dose is 50 mg daily.

Paroxetine should not be used by children and adolescents under the age of 18.

Elderly (more than 65 years)

Depending on your response the dose may be increased to 40 mg daily. The maximum dose is 40 mg daily.

Severe decreased kidney function

Your doctor prescribes a suitable dose for you.

Decreased liver function

Your doctor prescribes a suitable dose for you.

If you take more Paroxetine than you should

If you take more Paroxetine than you should, talk to your doctor or pharmacist or contact with the nearest hospital. Symptoms of overdose are, e.g. vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety and rapid heart rate.

If you forget to take Paroxetine

If you forget to take Paroxetine, omit the forgotten dose and take the next dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Paroxetine
Do not stop taking Paroxetine without consulting to your doctor, even if you feel better.

If you stop suddenly after taking this medicine for a long time you can experience withdrawal effects; you may feel dizzy, have sensory disturbances (numbness or 'pins and needles', called paraesthesia, electric shock sensations and ringing in the ears), sleep disturbances (including intense dreams), feeling sick (nausea), diarrhoea, headaches, rapid and irregular heart beat (palpitations), tremor, sweating, visual disturbances, or feeling agitated, anxious, irritable or confused about where you are (disoriented). These symptoms are generally mild to moderate and go away on their own within two weeks. However, in some patient these symptoms may be more severe, or go on for longer. They usually happen in the first few days after stopping the medicine.

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. 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 start taking your tablets again and come off them more slowly.

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.

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 1000 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 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 feelweak 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 Aggression.

- Some people have had thoughts of harming or killing
- themselves while taking Paroxetine or soon after stopping treatment (see Section 2, Before you take Paroxetine).
- Tooth grinding. 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
- 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 Paroxetin. 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.

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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
- 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 Fluid or water retention which may cause swelling of the arms or legs
- Painful erection of the penis that won't go away Unexpected bleeding, e.g bleeding gums, blood in urine or in
- Sensitivity to sunlight
- vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).

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.

Possible withdrawal effects when stopping treatment Very common side effects, likely to affect more than 1 in 10 people:

Feeling dizzy, unsteady or off-balance

- Feeling 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
 - Sleep disturbances (vivid dreams, nightmares, inability to sleep)
 - Feeling anxious

take Paroxetine.

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 withdrawl effects when stopping Paroxetine. 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 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 reach and sight of children.

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

This medicinal product does not require any special storage conditions 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.

- Each film-coated tablet contains
 - 20 mg of paroxetine (as paroxetine hydrochloride hemihydrate).
- Each film-coated tablet contains 30 mg of paroxetine (as paroxetine hydrochloride hemihydrate).
- The other ingredients are: Tablet core:

Calcium hydrogen phosphate, dihydrate Calcium hydrogen phosphate, anhydrous

Lactose monohydrate Sodium starch glycolate (Type A) Magnesium stearate (E470b)

Film-coating: 20 mg:

Titanium dioxide (E171) Hypromellose (E464)

Macrogol 400

Polysorbate 80 (E433) 30 mg:

Titanium dioxide (E171) Hypromellose (E464)

Macrogol 400 Indigo carmine aluminum lake (E 132) Polysorbate 80 (E433)

What Paroxetine looks like and contents of the pack

Film-coated tablets. 20 mg: Paroxetine 20 mg film-coated tablets are white coloured, capsule

on the other side.

shaped, biconvex tablets debossed with '56' on one side and 'C' with a deep break line on the other side. The tablet can be divided into equal halves. 30 mg:

Paroxetine 30 mg film-coated tablets are blue coloured, capsule

shaped, biconvex tablets debossed with an'F' on one side and '12'

Paroxetine 20 / Paroxetine 30 mg film-coated tablets are available in packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 98 100 and 250 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authourisation Holder

Milpharm Limited Ares, Odyssey Business Park

West End Road South Ruislip HA4 6QD United Kingdom Manufacturer

Milpharm Limited, Ares, Odyssey Business Park, West End Road, South Ruislip HA4 6QD United Kingdom

APL Swift Services (Malta) Limited HF26, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG 3000. This medicinal product is authorised in the Member States of

the EEA under the following names: Paroxetine Aurobindo 20 mg / 30 mg Cyprus: επικαλυμμένα με λεπτό υμένιο δισκία

Paroxetin Aurobindo 20 mg / 30 mg Filmtabletten Germany: Paroxetin "Aurobindo" Denmark: Paroxetine Aurobindo 20 mg / 30 mg õhukese

Estonia: polümeerikattega tabletid Ireland: Paroxetine Aurobindo 20 mg / 30 mg film-coated tablets Latvia: Paroxetin Aurobindo 20 mg / 30 mg apvalkotās

The Netherlands: Paroxetine Aurobindo 20 mg / 30 mg filmomhulde tabletten

Poland: Paroxetine Vitama Paroxetina Aurobindo Portugal PAROXETINA QUALIGEN 20 mg Spain:

United Kingdom: Paroxetine 20 mg / 30 mg film-coated tablets

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tabletes

Item Code Date & Time **Product Name** Component 27.08.2019 & 06:26 PM Paroxetine film-coated Leaflet P1522374 **Tablets** No. of Colours: 1 AUROBINDO Customer / Country Version No. Reason of Issue Packaging Development Milpharm_UK_ Unit-3 Dimensions Font Size Team Leader Font Type Ramesh A/s: 210 x 600 mm Initiator Kiranmai B/s: 60 x 35 mm Arial 9 pt Design vakils Agency 22374 Date - Designer - Run: Reviewed / Approved by 1. 27-AUG-2019 (Adi) - FR 15. 16. 17. REGULATORY AFFAIRS 11. 18. 12. 19. 13. 20. By PrityKumari at 11:21:11, 03/09/2019 Additional Information: Supercede Item Code: P1519663 Sign / Date

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