

Package leaflet: Information for the user

Paroxetine Aurobindo 20 mg film-coated tablets

Paroxetine Aurobindo 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:

1. What Paroxetine Aurobindo is and what it is used for
2. What you need to know before you take Paroxetine Aurobindo
3. How to take Paroxetine Aurobindo
4. Possible side effects
5. How to store Paroxetine Aurobindo
6. Contents of the pack and other information
- 7.

1. What Paroxetine Aurobindo is and what it is used for

Paroxetine Aurobindo belongs to a group of medicines called Selective Serotonin Reuptake Inhibitors (SSRIs), which are antidepressants.

Paroxetine Aurobindo is used in the treatment of:

- 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 chronic nervous worrying is prominent).
- Post-traumatic stress disorder (anxiety caused by a traumatic event).

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

Do not take Paroxetine Aurobindo

- 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 Aurobindo 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 Aurobindo

- Use in children and adolescents under 18 years of age:

Paroxetine Aurobindo 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 Aurobindo for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Paroxetine Aurobindo 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 Aurobindo. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioral development of Paroxetine Aurobindo in this age group have not yet been demonstrated.

In studies of Paroxetine Aurobindo 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 Aurobindo, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects when they stopped taking Paroxetine Aurobindo. These effects were mostly similar to those seen in adults after stopping Paroxetine Aurobindo (see Section 3, *How to take Paroxetine Aurobindo*, 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.

- 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 Aurobindo may make these feelings worse (see section “Possible side effects”).
- if you develop symptoms such as 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 Aurobindo. 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 Aurobindo 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 Aurobindo, you should contact your doctor.
- If your treatment for depression is electro convulsive therapy (ECT).
- 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 Aurobindo, 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 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)
- If you are taking tamoxifen to treat breast cancer (or fertility problems). Paroxetine Aurobindo 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.

Other medicines and Paroxetine Aurobindo

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 Aurobindo works, or make it more likely that you'll have side effects. Paroxetine Aurobindo 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 Aurobindo, inside this leaflet.
- Thioridazine or pimozide, which are anti-psychotics- see Do not take Paroxetine Aurobindo, 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 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 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 Aurobindo. They will know if it is safe for you to do so.

Paroxetine Aurobindo 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 Aurobindo. Alcohol may make your symptoms or side effects worse.

Pregnancy and, breast-feeding and fertility

Pregnancy:

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 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 Aurobindo while you are pregnant. However depending on your circumstances, your doctor may suggest that it is better for you to keep taking Paroxetine Aurobindo.

Make sure your midwife or doctor know you're taking Paroxetine Aurobindo. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Paroxetine Aurobindo 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. 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 happen 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 Aurobindo, 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 Aurobindo.

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 Aurobindo 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 Aurobindo contains lactose

Paroxetine Aurobindo 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 Aurobindo

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

Drink a glass of water with your medicine, preferably in the morning with food.
The tablet or tablet halves should be swallowed rather than 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.

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 Aurobindo than you should

If you take more Paroxetine Aurobindo 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 Aurobindo

If you forget to take Paroxetine Aurobindo, 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 Aurobindo

Do not stop taking Paroxetine Aurobindo 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 Aurobindo, 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 Aurobindo 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 Aurobindo, 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 medicine, 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 (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 (may affect up to 1 in 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 Aurobindo 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 (may affect up to 1 in 10,000 people):

- **Allergic reactions which may be severe to Paroxetine Aurobindo.** 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

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

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):

- 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 (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
- 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 Aurobindo. 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
- 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.

Very rare (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 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
- Unexpected bleeding, e.g bleeding gums, blood in urine or in 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 Aurobindo

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

Possible withdrawal effects when stopping treatment

Very common (may 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 take Paroxetine Aurobindo.
- 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 Aurobindo.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie <<http://www.hpra.ie>>; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paroxetine Aurobindo

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

This medicine 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 Aurobindo 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 Aurobindo looks like and contents of the pack

Film-coated tablets.

20 mg:

Paroxetine Aurobindo 20 mg film-coated tablets are white coloured, capsule 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 Aurobindo 30 mg film-coated tablets are blue coloured, capsule shaped, biconvex tablets debossed with an 'F' on one side and '12' on the other side.

Paroxetine Aurobindo 20 / Paroxetine Aurobindo 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 Authorisation Holder

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or

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This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus:	Paroxetine Aurobindo 20 mg / 30 mg επικαλυμμένα με λεπτό υμένιο δισκία
Germany:	Paroxetin Aurobindo 20 mg / 30 mg Filmtabletten
Denmark:	Paroxetin “Aurobindo”
Estonia:	Paroxetin Aurobindo, 20 mg / 30 mg õhukese polümeerikattega tabletid
Spain:	PAROXETINA QUALIGEN 20 mg / comprimidos recubiertos con película
Ireland:	Paroxetine Aurobindo 20 mg / 30 mg film-coated tablets
Latvia:	Paroxetin Aurobindo 20 mg / 30 mg apvalkotās tabletes
The Netherlands:	Paroxetine Aurobindo 20 mg / 30 mg filmomhulde tabletten
Poland:	Paroxetine Aurobindo
Portugal	Paroxetina Aurobindo
United Kingdom:	Paroxetine 20 mg / 30 mg film-coated tablets

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