

Package leaflet: Information for the patient

Paroxetin Actavis 20 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 Paroxetin Actavis is and what it is used for
2. What you need to know before you take Paroxetin Actavis
3. How to take Paroxetin Actavis
4. Possible side effects
5. How to store Paroxetin Actavis
6. Contents of the pack and other information

1. What Paroxetin Actavis is and what it is used for

Paroxetin Actavis is a treatment for adults with depression and/or anxiety disorders.

The anxiety disorders that Paroxetin Actavis 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),
- generalised anxiety disorder (generally feeling very anxious or nervous).

Paroxetin Actavis is one of a group of medicines called SSRIs (selective serotonin re-uptake inhibitors). It is not fully understood how Paroxetin Actavis 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 Paroxetin Actavis

Do not take Paroxetin Actavis

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Paroxetin Actavis.

- Are you taking any other medicines (see “Other medicines and Paroxetin Actavis”, inside this leaflet)?

- Are you taking tamoxifen to treat breast cancer <or fertility problems>? Paroxetin Actavis 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 an abnormality of your heart tracing after an electrocardiogram (ECG) known as prolonged QT interval?
- Do you have a family history of QT prolongation, heart disease such as heart failure, low heart rate, or low potassium levels or low magnesium levels?
- 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 pregnant (see “Pregnancy, breast-feeding and fertility”), 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)?
- Do you have diabetes?
- Are you on a low sodium diet?
- Do you have glaucoma (pressure in the eye)?
- Are you pregnant or planning to get pregnant (see “Pregnancy, breast-feeding and fertility” inside this leaflet)?
- Are you under 18 years old (see “Children and adolescents under 18”, inside this leaflet)?

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

Children and adolescents under 18

Paroxetin Actavis 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 Paroxetin Actavis. If your doctor has prescribed Paroxetin Actavis for you (or your child) and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when you (or your child) are taking Paroxetin Actavis. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Paroxetin Actavis 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). In addition, patients under 18 also commonly (may affect up to 1 in 10 people) 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 Paroxetin Actavis

Some patients who take /.../ 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 /.../, see section 4.

Other medicines and Paroxetin Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way Paroxetin Actavis works, or make it more likely that you'll have side effects. Paroxetin Actavis 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 /.../", inside this leaflet,
- Medicines known to increase the risk of changes in the electrical activity of the heart (e.g. the **anti-psychotics** thioridazine or pimozide) - see "Do not take /.../", 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 and tricyclic antidepressants like clomipramine, nortriptyline and desipramine,
- **Dietary supplements** called tryptophan and oxitriptan (also known as 5-hydroxytryptophan),
- 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.

Paroxetin Actavis with food, drink and alcohol

Do not drink alcohol while you are taking Paroxetin Actavis. Alcohol may make your symptoms or side effects worse.

Taking Paroxetin Actavis in the morning with food will reduce the likelihood of you feeling sick (nausea).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

In babies whose mothers took Paroxetin Actavis during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to up to 2 in 100 babies in mothers who took Paroxetin Actavis. You and your doctor may decide that it is better for you to change to another treatment or to gradually stop taking Paroxetin Actavis while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking Paroxetin Actavis.

Make sure your midwife or doctor knows you're taking Paroxetin Actavis. When taken during pregnancy, particularly late pregnancy, medicines like Paroxetin Actavis 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 Paroxetin Actavis 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 Paroxetin Actavis 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 Paroxetin Actavis so they can advise you.

Paroxetine may get into breast milk in very small amounts. If you are taking Paroxetin Actavis, 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're taking Paroxetin Actavis.

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 Paroxetin Actavis include dizziness, confusion, feeling sleepy or blurred vision. If you do get these side effects, do not drive or use machinery.

Paroxetin Actavis contains soya lecithin and sodium

If you are allergic to peanut or soya, do not use this medicine.

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

3. How to take Paroxetin Actavis

Always take this medicine exactly as your doctor 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. This table will show you how many tablets to take.

Dose	Number of tablets to take
10 mg	Half a tablet
20 mg	One tablet
30 mg	One-and-a-half tablets
40 mg	Two tablets
50 mg	Two-and-a-half tablets
60 mg	Three tablets

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	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 Paroxetin Actavis. 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. It will reduce the likelihood of you feeling sick (nausea).

Swallow them with a drink of water.

Do not chew.

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

Older people

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

Patients with liver or kidney disease

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

If you take more Paroxetin Actavis 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 a hospital straight away. Show them the pack of tablets.

Someone who has taken an overdose of Paroxetin Actavis 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 Paroxetin Actavis

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

Paroxetin Actavis 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 Paroxetin Actavis

Do not stop taking Paroxetin Actavis until your doctor tells you to.

When stopping Paroxetin Actavis, 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 Paroxetin Actavis you take by 10 mg a week. Most people find that any symptoms on stopping Paroxetin Actavis 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 Paroxetin Actavis, 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 Paroxetin Actavis.

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 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 side effects (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 Paroxetin Actavis.

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 Paroxetin Actavis.

If you get any of the following side effects, stop taking the medicine and tell your doctor or go to the casualty department at your nearest hospital straight away.

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

- **Unusual bruising or bleeding**, including vomiting blood or passing blood in your stools.
- **Not able to pass water.**

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

- **Seizures (fits).**
- **If you feel restless and feel like you can't sit or stand still**, you may have something called akathisia. Increasing your dose of /.../ may make these feelings worse.
- **If you feel tired, 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 to /.../.**
The symptoms include: a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, itching, difficulty breathing (shortness of breath) or swallowing and feeling weak or lightheaded resulting in collapse or loss of consciousness.
- **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.
- **Acute glaucoma** (the symptoms include: painful eyes and blurred vision).
- **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)

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

- Some people have had thoughts of harming or killing themselves while taking /.../ or soon after stopping treatment (see "Warnings and precautions").
- Some people have experienced aggression while taking /.../.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see "Pregnancy, breast-feeding and fertility" in section 2 for more information.

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):

- Reduction in white blood cell count
- A brief increase in blood pressure, or a brief decrease that may make you feel dizzy or faint when you stand up suddenly
- A faster than normal heartbeat
- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue
- Dilated pupils
- Skin rashes
- Itching
- Feeling confused
- Having hallucinations (strange visions or sounds)
- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence)
- If you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking /.../. 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
- 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):

- 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 (increases risk of bleeding or bruising)

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

- Tooth grinding
- Inflammation of the colon (causing diarrhoea)

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

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Paroxetin Actavis

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 label or carton after “EXP”. The expiry date refers to the last day of that month.

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 Paroxetin Actavis contains

- The active substance is paroxetine.
Each film-coated tablet contains 20 mg paroxetine (as hydrochloride).
- The other ingredients are: magnesium stearate, sodium starch glycolate, mannitol (E421), microcrystalline cellulose, polymetacrylate, polyvinyl alcohol, talc, soya lecithin (E322), xanthan gum (E415) and titanium dioxide (E171).

What Paroxetin Actavis looks like and contents of the pack

Paroxetin Actavis film-coated tablets are white and scored.

Pack sizes

Blister packs 20, 50, 60 and 100 tablets. 5x20 and 10x20 film-coated tablets.

Plastic bottle 20, 60, 100, 200 and 250 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

Iceland: Paxetin

Sweden: Paroxetin Actavis

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