

PAXTINE®

paroxetine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PAXTINE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PAXTINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PAXTINE is used for

This medicine contains the active ingredient paroxetine.

This medicine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRI) antidepressants. They are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Depression is longer lasting or more severe than the 'low moods' that everyone has from time to time. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms. You may feel low in spirit, lose interest in your usual activities, be unable to enjoy life, have a poor appetite or over

eat, have disturbed sleep, often waking up early, low energy and feel guilty over nothing.

PAXTINE may be used to treat irrational fears or obsessional behaviour. These can also be due to chemical imbalance in parts of the brain.

PAXTINE may be used to help prevent panic attacks.

PAXTINE may be used to treat patients who may avoid and/or are fearful of social situations.

Your doctor may decide that you should continue to use PAXTINE for some time, even when you have overcome your problem. This should prevent the problem from returning.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take PAXTINE

Antidepressants can increase suicidal thoughts and actions in some children and adolescents younger than 18 years of age.

Suicidal thoughts and actions can also be caused by depression, a serious medical condition that is commonly treated with antidepressants. Thinking about killing yourself or trying to kill yourself is called suicidality or being suicidal.

Antidepressants are used to treat depression and other illnesses. It

is important to discuss all the risks of treating depression and the risks of not treating it. You should discuss all treatment choices with your doctor, not just the use of antidepressants.

Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present (see Use in Children and Adolescents below).

When you must not take it

Do not take PAXTINE if you have an allergy to:

- any medicine containing paroxetine
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant or intend to become pregnant.

Studies show that use of paroxetine in early pregnancy (first 13 weeks) may be associated with an increased risk of some birth defects in babies.

If you become pregnant or intend to become pregnant while taking paroxetine, you should make an appointment to see your doctor and have your treatment reviewed.

It is important that you do not stop taking paroxetine suddenly.

Paroxetine is a medicine that can have withdrawal side effects if stopped suddenly (see Unwanted Effects That May Occur on Stopping Treatment below).

If you have taken PAXTINE before and became unwell after taking it, tell your doctor or pharmacist before you take the first dose.

Do not take this medicine if you are taking any other medications for the treatment of depression or have done so in the last 14 days.

Taking PAXTINE with another antidepressant may cause a serious reaction.

You must not take PAXTINE for 14 days after stopping monoamine oxidase inhibitor drugs (MAOIs). Taking PAXTINE with a MAOI may cause a serious reaction.

Examples of MAOIs are phenelzine and tranylcypromine. Another MAOI includes the antibiotic linezolid.

Do not take this medicine if you are taking or have recently taken (within the last two weeks) a medicine called methylthioninium chloride (methylene blue).

Do not take this medicine if you are taking:

- thioridazine
- pimozide

Taking PAXTINE together with either of the above medicines, which are medicines used to treat schizophrenia, can lead to serious side effects.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are over 65 years of age be aware as PAXTINE may cause a reduction in the amount of sodium within your blood. This can lead to sleepiness and muscle weakness.

If you experience these symptoms, tell your doctor or pharmacist as soon as possible.

Medicines like PAXTINE may affect your sperm.

Fertility in some men may be reduced while taking this medicine.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- heart problems
- epilepsy
- mania
- glaucoma (raised pressure in the eye)
- problems with blood clotting
- other psychiatric conditions (bipolar disorder)
- diabetes

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking PAXTINE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PAXTINE may interfere with each other. These include:

- medicines used to treat depression, anxiety, schizophrenia or attention-deficit hyperactivity disorder (ADHD) including tryptophan, St John's Wort (*hypericum perforatum*), perphenazine, risperidone, lithium or atomoxetine
- medicines used in anaesthesia or to treat pain or chronic pain, such as tramadol or fentanyl
- medicines used to control epilepsy (known as anticonvulsants), such as phenytoin, carbamazepine, phenobarbital (phenobarbitone)
- medicines used to treat migraine attacks such as sumatriptan
- medicines used to thin blood (anti-coagulants) such as warfarin, aspirin, non-steroidal anti-inflammatory drugs (NSAIDs)
- certain medicines used to treat Parkinson's disease such as selegiline and procyclidine
- medicines used to lower blood pressure or treat heart conditions, such as metoprolol or flecainide
- cimetidine, a medicine used to treat stomach ulcers
- medicine to treat or prevent breast cancer such as tamoxifen
- medicines used to treat HIV infection such as a combination of fosamprenavir and ritonavir
- medicines used for anaesthesia, such as mivacurium and suxamethonium

These medicines may be affected by PAXTINE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take PAXTINE

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The usual dose of PAXTINE for depression and social anxiety disorder/social phobia is one 20 mg tablet per day.

To treat obsessions and compulsions or panic attacks, the usual dose of PAXTINE is two 20 mg tablets (40 mg) per day.

Your doctor may start you on a lower dose (half a tablet) and increase the dose slowly over several weeks. This may require you to break the tablet in half.

How to take it

Take the tablets with a full glass of water or another liquid.

Do not crush or chew the tablets.

PAXTINE tablets can be divided in half along the breakline if required.

When to take it

Take your medicine in the morning, preferably with food.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Like other drugs of this class, PAXTINE will not relieve your symptoms immediately. People generally start feeling better in a few weeks.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of

harming yourself or committing suicide.

It is possible that these symptoms may continue or increase until the full antidepressant effect of your medicine becomes apparent.

Tell your doctor immediately or go to your nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Tell your doctor if you experience any worsening of your depression/ other symptoms at any time during your treatment.

Stopping treatment

Do not stop taking your medicine even if you begin to feel better.

Your doctor may decide that you should continue to use PAXTINE for some time, even when you have overcome your problem.

For best effect, PAXTINE must be taken regularly.

Your doctor will tell you when and how PAXTINE should be stopped.

Treatment is usually stopped by slowly reducing the dosage over a period of several weeks. When you stop treatment with this medicine, especially if this is done suddenly, you may experience unwanted symptoms.

Use in children and adolescents

PAXTINE is not recommended for use in children and adolescents under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established and there are possible unwanted effects.

Information from clinical trials has suggested that young adults, particularly those with depression, may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with PAXTINE, especially during initial

treatment (generally the first one to two months).

The majority of attempted suicides in clinical trials in depression involved patients aged 18 to 30 years.

Family and caregivers of children and adolescents being treated with antidepressants for major depressive disorder or for any other condition (psychiatric or non-psychiatric) need to monitor them for the emergence of agitation, irritability, unusual changes in behaviour, as well as the emergence of thoughts of suicide, and to report such symptoms immediately to their doctor.

It is particularly important that monitoring be undertaken during the initial few months of antidepressant treatment or at times of dose increase or decrease.

Use in pregnancy

If you take PAXTINE near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have history of bleeding disorders. Your doctor or midwife should be aware that you are taking PAXTINE so they can advise you.

If you forget to take it

Skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for

advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much PAXTINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking PAXTINE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PAXTINE.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

Persons taking PAXTINE may be more likely to think about killing themselves or actually trying to do so, especially when PAXTINE is first started or the dose is changed.

People close to persons taking PAXTINE can help by paying attention to changes in user's moods or actions.

Contact your doctor right away if someone using PAXTINE talks about or shows signs of killing him or herself. If you are taking

PAXTINE yourself and you start thinking about killing yourself, tell your doctor about this side effect right away.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to do some blood tests and check your heart and blood pressure from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not stop taking PAXTINE without your doctor's permission.

Suddenly stopping PAXTINE may cause symptoms like dizziness, trouble sleeping, shaking, feeling anxious, nausea, sweating or tinnitus.

Do not take PAXTINE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how PAXTINE affects you.

Tests have shown that PAXTINE does not have a marked effect on driving ability. However, this medicine may cause drowsiness, dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking moderate amounts of alcohol is unlikely to affect your response to PAXTINE, however it is best to avoid alcohol while you are taking this medicine.

There is an increased risk of breaking a bone in people taking medicines like PAXTINE.

This risk is greatest during the early stages of treatment.

When your doctor decides that you should stop taking PAXTINE, the dose will be

reduced slowly or the time between doses increased over 1 or 2 weeks.

Some people may have symptoms such as dizziness, anxiety, sleep disturbances, pins and needles, electric shock sensations or feeling sick and sweating if this medicine is stopped, particularly if stopped suddenly.

Although PAXTINE is not recommended for children under 18 years of age, additional symptoms have been experienced by children whilst stopping treatment including abdominal pain, nervousness and mood changes.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PAXTINE.

This medicine helps most people who take it, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

MILD EFFECTS

Tell your doctor if you notice any of the following and they worry you:

- feeling sick, dry mouth, constipation, decreased appetite, diarrhoea
- vomiting
- dizziness, drowsiness or difficulty getting to sleep
- impaired sexual function
- weakness
- feeling sweaty or shaky
- bruising

- abnormal dreams (including nightmares)
- weight gain

MORE SERIOUS EFFECTS

Tell your doctor as soon as possible if you notice any of the following:

- muscle spasms or twitches

If any of the following happen, stop taking PAXTINE and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reaction including, swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing
- skin rash, which may blister, and looks like small targets (central dark spots surround 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 or on much of the body surface (Stevens-Johnson syndrome or toxic epidermal necrolysis)
- sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- sudden increase in body temperature, severe convulsions
- fast heart beat, sweating, muscle spasm, racing thoughts, restlessness

Other rare events that have been reported with PAXTINE use include:

- blurred vision
- abnormal liver function
- low levels of sodium in the blood, especially in older people
- bleeding disorders, including nose bleeds and gastrointestinal bleeding which occurs very rarely
- hormone disturbances

- mood of excitement, over-activity and uninhibited behaviour
- confusion
- seizures
- rash caused by light
- itchy rash, hives, swelling of the face, lips, mouth, tongue or throat
- akathisia (restlessness or difficulty keeping still, caused by medicines to treat mental disorders)
- irresistible urge to move the legs (Restless Legs Syndrome)
- menstrual period disorder (including heavy periods, bleeding between periods and absence of periods)
- severe allergic reactions
- heavy vaginal bleeding shortly after birth

Unwanted effects that may occur on stopping treatment may include:

- dizziness
- sensory disturbances such as pins and needles, burning sensations and electric shock-like sensations
- sleep disturbances, including intense dreams
- agitation or anxiety
- feeling sick
- shaking or tremors
- confusion
- headache
- sweating
- diarrhoea

These are likely to occur in the first few days of stopping treatment or, very rarely, if you miss a dose.

They are more likely to occur if you stop taking PAXTINE suddenly.

Always consult your doctor before stopping your medicine.

For most patients, symptoms go away on their own within a few weeks. However, if you feel that the unwanted symptoms are too severe, tell your doctor who will suggest

how to manage stopping treatment more slowly.

Additional symptoms that have been experienced by children and adolescents under the age of 18 years whilst stopping treatment include changing emotions (thoughts of suicide, attempting suicide, mood changes and feeling tearful), abdominal pain and nervousness.

Tell your doctor immediately if you notice any of the following:

- **wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**

Although this medicine is not recommended for children and adolescents below 18 years of age, the most common side effects 18 are:

- decreased appetite
- tremor (uncontrollable trembling)
- sweating
- hyperactivity
- hostile/unfriendly behaviour
- agitation
- changing emotions, including crying, changes in mood, trying to harm themselves, thoughts of suicide and attempting suicide

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some people.

After taking PAXTINE

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store PAXTINE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in November 2023.

Australian Registration Number:

AUST R 227120

PAXTINE® is a Viatris company trade mark

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Product description

What it looks like

PAXTINE is a white, round film-coated tablet marked P/2 and G.

Each pack contains 30 tablets.

Ingredients

PAXTINE contains 20 mg of paroxetine as the active ingredient.

The tablets also contain the following inactive ingredients:

- calcium hydrogen phosphate
- colloidal anhydrous silica
- magnesium stearate
- methacrylic acid copolymer (Trade Name: Eudragit E 100)
- purified talc
- sodium starch glycollate
- titanium dioxide (171)

PAXTINE also contains sulfites.

This medicine does not contain sucrose, lactose, gluten or tartrazine.

Manufacturer

PAXTINE is made in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road