

PAXTINE

Paroxetine Tablets 20mg



What is in this leaflet

This leaflet answers some common questions about PAXTINE.

It does not contain all the information available on this medicine. 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 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 want to read it again.

What PAXTINE is used for

Your PAXTINE tablets contain the active ingredient, paroxetine hydrochloride. Paroxetine belongs to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs).

PAXTINE is normally used to treat major depressive disorder (MDD) and help prevent potential recurrence of the symptoms of depression. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

PAXTINE is also used to treat the following conditions: Obsessive

Compulsive Disorder, Panic Disorder, Social Anxiety Disorder/Social Phobia, Generalised Anxiety Disorder and Post-traumatic Stress Disorder.

Your doctor, however, may have prescribed PAXTINE for another purpose. Ask your doctor if you have any questions about why PAXTINE has been prescribed for you.

The use of this medicine in children and adolescents under the age of 18 years is not recommended.

PAXTINE is available only with a doctor's prescription.

Before you take PAXTINE

When you must not take it

Do not take PAXTINE if you:

- are allergic to paroxetine hydrochloride or any other ingredients listed at the end of this leaflet.

Do not take PAXTINE if you are taking:

- **thioridazine** (an antipsychotic medicine)
- **pimozide** (an antipsychotic medicine)
- **linezolid** (a medicine used to treat infections)
- **another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days.** Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

Before you start to take it

You must tell your doctor if you:

- have had an allergic reaction to any medicine that you have taken previously to treat your current condition
- are allergic to any other medicines, foods, preservatives or dyes
- have thoughts about harming yourself (suicidal thoughts or tendencies), or you have had them in the past
- have or ever had any other health problems, including:
 - heart, liver or kidney problems
 - diabetes
 - seizures, fits or convulsions (epilepsy)
 - mania (mood with excitement, over-activity and uninhibited behaviour) or a history of mania
 - raised pressure in the eye (glaucoma)
 - problems with bleeding or blood clotting.
 - low blood potassium levels
 - low blood magnesium levels

Tell your doctor if you are pregnant, plan to become pregnant or you are breastfeeding. Your doctor will discuss with you the risks and benefits of taking PAXTINE if you are pregnant or breastfeeding.

Paroxetine should be used with caution in patients at risk of irregular heart beat (e.g. QTc prolongation and Torsades de Pointes). Your doctor may wish to perform tests on the electrical activity of your heart prior to starting or during your treatment.

If you have not told your doctor about any of the above, or any other medical conditions, tell him/her before you start taking PAXTINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, or have taken any other medicines in the past two weeks, including any that you buy without a prescription from your pharmacy, supermarket or health shop.

Some medicines that may interfere with PAXTINE include:

- **other antidepressant medicines known as:**
 - **monoamine oxidase Inhibitors (MAOIs)** (e.g. phenelzine and tranylcypromine)
 - **selective serotonin reuptake inhibitors (SSRIs)** (e.g. citalopram and fluoxetine)
 - **tricyclic antidepressants** (e.g. amitriptyline and imipramine)
- **other serotonergic drugs** (e.g. tramadol, fentanyl and lithium)
- **methylionium chloride** (methylene blue)
- **metoprolol** (a medicine used to lower blood pressure)
- **medicines used to regulate your heart beat** (e.g. flecainide and propafenone)
- **medicines used to control epilepsy** (e.g. phenytoin and carbamazepine)
- **antipsychotic drugs** (e.g. thioridazine, perphenazine and pimozide)
- **atomoxetine** (a medicine used to treat attention deficit hyperactivity disorder (ADHD))
- **risperidone** (a medicine used to treat schizophrenia)
- **procyclidine** (a medicine used to treat Parkinson's disease)
- **triptans such as sumatriptan** (a medicine used to treat migraines)
- **warfarin** (a medicine used to prevent blood clots)
- **medicines used to treat inflammation and pain known as non-steroidal anti-inflammatory drugs or NSAIDs** (e.g. ibuprofen, diclofenac, ketoprofen)

- **aspirin** (a medicine used to treat inflammation and pain, and to prevent blood clots)
- **linezolid** (a medicine used to treat infections)
- **tamoxifen** (a medicine used to treat breast cancer).

These medicines may be affected by PAXTINE or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Hypericum perforatum (St John's Wort) should be avoided as adverse interactions have been reported with a range of drugs, including antidepressants.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking PAXTINE.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take PAXTINE

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

How much to take

Take PAXTINE exactly as your doctor has prescribed.

Your doctor will tell you how many PAXTINE tablets to take and when to take them each day. It is important that you take PAXTINE as directed by your doctor. Do not take more than the recommended dose.

It usually takes 2 to 3 weeks before any response to PAXTINE is noticeable.

For the treatment of major depressive disorder, social anxiety disorder/social phobia, generalised anxiety disorder and post-traumatic stress disorder, the usual dose of PAXTINE is 20 mg daily. Depending on your response, your doctor may

increase your dose to a maximum of 50mg daily.

For the treatment of obsessive compulsive disorder, the usual dose of PAXTINE is 40mg daily, however your doctor may increase your dose up to a maximum of 60mg daily.

For the treatment of panic disorder, the usual dose of PAXTINE is 40mg daily, however your doctor may increase your dose up to a maximum of 60mg daily.

How and when to take it

PAXTINE tablets should be swallowed whole with a glass of water. **Do not crush or chew the tablets but they can be halved.**

It is recommended that PAXTINE is taken once daily in the morning, preferably with food.

How long to take it

Continue to take PAXTINE even if it takes some time before you feel any improvement in your condition.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take PAXTINE for several months or even longer to make sure the benefits will last.

Continue taking your medicine until your doctor tells you to stop, even if you begin to feel better.

The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return.

If you forget to take it

If you forget to take a dose, take it as soon as you remember. **Do not take more than one dose at a time to make up for the dose you missed.** This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, or have any questions, ask your doctor or pharmacist.

Taking your medicine at the same time each day may help you to remember to take it regularly. 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 National Poisons Information Centre (0800 POISON or 0800 764 766) 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. Take the pack of PAXTINE with you if you can.

While you are taking PAXTINE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking PAXTINE.

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

If you are pregnant, plan to become pregnant or are breastfeeding, tell your doctor or pharmacist.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like PAXTINE 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. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you plan to have surgery, including dental surgery, tell your doctor (including surgeon and/or anaesthetist) or dentist that you are taking PAXTINE.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity, restlessness or difficulty sitting still, hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.

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 paroxetine. 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.

If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm
- increase in aggressive behaviour, irritability or any

other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not drive or operate machinery until you know how PAXTINE affects you.

PAXTINE can cause drowsiness, dizziness or fatigue in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that PAXTINE does not affect your performance.

Do not stop taking PAXTINE or lower the dose without first checking with your doctor.

Stopping PAXTINE suddenly may cause dizziness, headache and nausea. Your doctor may want you to gradually reduce the amount of PAXTINE you are taking before stopping completely.

Do not use PAXTINE to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Be careful when drinking alcohol while taking PAXTINE.

Combining PAXTINE and alcohol may make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while being treated with PAXTINE.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

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

- nausea, diarrhoea, vomiting or constipation
- dizziness or drowsiness
- dry mouth
- sweating
- decreased appetite
- weight gain
- difficulty sleeping
- agitation
- tremor
- blurred vision
- yawning
- sexual problems (In some cases these symptoms have continued after stopping treatment)
- weakness or loss of strength
- headache
- fever
- general ill feeling
- itching of the skin
- joint aches
- skin rash

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

- abnormal bleeding or bruising
- yellowing of the skin and/or eye (also called jaundice)

The above list includes some serious side effects and may require medical attention.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- symptoms of an allergic reaction such as skin rash, blistering, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- symptoms of Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea and muscle spasms. Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of PAXTINE with other medicines, such as SSRIs (refer to *Taking other medicines* section)

- symptoms of “shock” such as rapid, shallow breathing; cold, clammy skin; a rapid, weak pulse; dizziness, weakness and fainting
- sudden increase in body temperature, severe convulsions
- heart palpitations, feeling faint or collapsing
- fits or seizures (convulsions)
- muscle spasms or twitches
- seeing, hearing or feeling things that are not there (hallucinations)
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm

These may be serious side effects. You may need urgent medical attention.

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

This medicine 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. Discuss this with your doctor if necessary.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you should suffer from any of these side effects or any other undesired effect, please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking PAXTINE

Storage

Always keep your PAXTINE tablets in the original blister pack and out of sight and reach of children. Store in a cool dry place where the

temperature stays below 25°C and protect from light, heat and moisture.

Do not store PAXTINE, or any other medicine, in the bathroom, on windowsills or in the glove box of the car. Do not refrigerate or freeze your PAXTINE tablets.

Do not use this medicine after the expiry date shown on either the outer pack or blister pack.

Disposal

If your doctor tells you to stop taking PAXTINE, or your tablets have passed their expiry date, ask your pharmacist what to do with the remaining tablets.

Product Description

What PAXTINE tablets look like

PAXTINE is a convex, white film coated tablet marked “PI2” on one side and “G” on the other.

Ingredients

Active ingredient:

Paxtine contains 22.22mg of the active ingredient, paroxetine hydrochloride, corresponding to 20mg paroxetine base.

Inactive ingredients:

Paxtine also contains:

- calcium hydrogen phosphate
- colloidal anhydrous silica
- magnesium stearate
- methacrylic acid copolymer
- purified talc
- sodium starch glycollate
- titanium dioxide

PAXTINE is gluten free and lactose free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 579 811

Date of information

30 September 2020 (Based on
datasheet dated 30 September
2020)