

## Paxtine

contains the active ingredient paroxetine (hydrochloride anhydrate)

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Paxtine.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Paxtine against the benefits expected for you.

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

**Keep this leaflet with your medicine.**

You may need to read it again.

#### What is Paxtine used for

The name of your medicine is Paxtine; it is also known as paroxetine.

Paxtine belongs to a group of medicines called selective serotonin reuptake inhibitor (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 usual activities, be unable to enjoy life, have poor appetite or over eat, have disturbed sleep, often waking up early, low energy and feel guilty over nothing.

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

Paxtine may also be used to help prevent panic attacks.

Paxtine may also 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.

Your doctor may have prescribed Paxtine for another use. Ask your doctor if you have any questions about why Paxtine has been prescribed for you.

#### Before you take Paxtine

Antidepressants can increase suicidal thoughts and actions in some children and adolescents younger than 18 years of age. But 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. Depression and other illnesses can lead to suicide. In some children and adolescents, treatment with an antidepressant increases suicidal thinking or actions. It is important to discuss all the risks of treating depression and also 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").

**Do not take it if:**

**You must not take Paxtine 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").

**Do not take Paxtine if you have ever had an allergic reaction to paroxetine (hydrochloride anhydrate) or any of the ingredients listed toward the end of this leaflet (see "Ingredients").**

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

**If you have taken Paxtine before and became unwell, tell your doctor or pharmacist before taking the first dose.**

**Do not take Paxtine 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 until 14 days after stopping monoamine oxidase inhibitor drugs (MAOIs).**

Examples of MAOIs are phenelzine and tranylcypromine. Another MAOI includes the antibiotic linezolid. There may be others so please check with your doctor. Taking Paxtine with a MAOI may cause a serious reaction.

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

**Do not take Paxtine if you are taking:**

- thioridazine (Aldazine, Melleril)
- pimozone (Orap).

Taking Paxtine together with either thioridazine or pimozone, which are medicines used to treat schizophrenia, can lead to serious side effects.

**Do not take this medicine after the expiry date (EXP) printed on the pack has passed 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.

**Take special care with Paxtine if you are over 65 years of age as Paxtine may cause a reduction in the amount of sodium**

**within your blood which can lead to sleepiness and muscle weakness. If you experience these symptoms, please consult your doctor as soon as possible.**

**Medicines like Paxtine may affect your sperm. Fertility in some men may be reduced while taking Paxtine.**

**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 are allergic to foods, dyes, preservatives or any other medicines.**

**Tell your doctor if you are pregnant or intend to become pregnant.**

**Tell your doctor if you are breastfeeding or wish to breastfeed.**

Your doctor will discuss with you the possible risks and benefits of using Paxtine during breastfeeding.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

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

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 if you are taking any other medicines, including medicines you buy without a prescription. In particular tell your doctor if you are taking any of the following medicines:**

- medicines used to treat depression, anxiety, schizophrenia or attention-deficit hyperactivity disorder (ADHD) including medicines you buy without a doctor's prescription such as tryptophan, St John's Wort (hypericum perforatum), perphenazine, risperidone, lithium or atomoxetine.
- medicines used in anaesthesia or to treat pain or chronic pain, specifically tramadol or fentanyl.
- medicines used to control epilepsy (anticonvulsants), such as phenytoin, carbamazepine, phenobarbital.
- 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, specifically tamoxifen
- medicines used to treat HIV infection such as a combination of fosamprenavir and ritonavir.
- medicines used to anaesthesia, such as mivacurium and suxamethonium.

Some medicines may affect the way other medicines work.

Your doctor and pharmacist will be able to tell you which medicines are safe to take with Paxtine.

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## How to take Paxtine

### Follow your doctor's instructions about how and when to take Paxtine.

Read the direction label carefully. If you have any concerns about how to take Paxtine, talk to your doctor or pharmacist.

#### *How much to take*

The usual dose of Paxtine for depression and social anxiety disorder/social phobia is one 20 mg tablet per day. Your doctor may increase the dose slowly over several weeks. This may require you to break the tablet in half.

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 Paxtine with a full glass of water or another liquid.

Do not crush or chew the tablets. Paxtine tablets, however, can be divided in half along the breakline if advised by your doctor or pharmacist.

#### *When to take it*

**Paxtine should be taken 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 for*

**Keep taking your Paxtine for as long as your doctor tells you.**

Like other drugs of this type, Paxtine will not relieve your symptoms straight away. People generally start feeling better in a few weeks or so. 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 the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time. Also contact your doctor if you experience any worsening of your depression/other symptoms at any time during your treatment.

#### *Stopping Treatment*

**Do not stop taking Paxtine 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 discontinued.

Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with Paxtine, especially if this is done suddenly, you may experience unwanted symptoms. Please see the section of this leaflet called "Unwanted effects that may occur on stopping treatment".

#### *Use in children and adolescents*

**Paxtine is not recommended for use in children and adolescents under 18 years.**

**The use of Paxtine is not recommended to treat depression in children and adolescents under 18, as the drug has not been shown to be effective in this age group 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.

#### *If you forget to take it*

**Do not take an extra dose. Wait until the next day and take your normal dose then.**

**Do not try to make up for the dose that you missed by taking more than one dose at a time.**

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

**If you have trouble remembering when 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 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.

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## While you are taking Paxtine

### *Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Paxtine.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Paxtine.**

**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 as it should and change your treatment unnecessarily.

#### *Things you must not do*

**Do not use Paxtine to treat any other complaints unless your doctor says to.**

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

#### *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, Paxtine may cause drowsiness, dizziness or lightheadedness in some people. Make sure you know how you react to Paxtine before you drive a car or operate machinery.

**Although drinking moderate amounts of alcohol is unlikely to affect your response to Paxtine, 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 may 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 Paxtine is stopped, particularly if stopped suddenly.**

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

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## Side effects

**Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Paxtine, even if the problem is not listed below.**

Like other medicines, Paxtine can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

### **MILD EFFECTS**

**Tell your doctor if you notice any of the following that are troublesome or ongoing:**

- feeling sick, dry mouth, decreased appetite, diarrhoea or constipation
- vomiting
- weakness
- dizziness, drowsiness or difficulty getting to sleep
- feeling sweaty or shaky
- bruising
- abnormal dreams (including nightmares)
- impaired sexual function
- weight gain.

### **MORE SERIOUS EFFECTS**

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

- muscle spasms or twitches

**Stop taking Paxtine and contact your doctor or go to Accident and Emergency at the nearest hospital if any of the following happens:**

- 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 (Stevens-Johnson syndrome)
- a widespread rash with blisters and skin peeling on much of the body surface (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 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.

**Unwanted effects that may occur on stopping treatment.**

Symptoms 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. However, they are more likely to occur if you stop taking Paxtine too quickly. Therefore, always consult your doctor before stopping your medicine. For the majority of patients, symptoms go away on their own within a few weeks. However, if you feel that the unwanted symptoms are too severe, see your doctor who will suggest how to manage stopping treatment more slowly.

Additional symptoms that have been experienced by children whilst stopping treatment are changing emotions (including 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 Paxtine is not recommended for children and adolescents below 18 years of age, the most common unwanted effects in children under 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.

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.

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

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## After taking Paxtine

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### Storage

**Keep Paxtine 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.

**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 Paxtine in the car or on window sills.**

Heat and dampness can destroy some medicines.

### 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 any that are left over.**

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## Product description

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### What it looks like

Paxtine is a convex, white film coated tablet marked "P|2" on one side and "G" on the other.

Each pack contains 30 tablets.

### Ingredients

The active ingredient in Paxtine is paroxetine (as hydrochloride anhydrate).

Each Paxtine tablet contains 20 mg of paroxetine.

The tablets also contain the following inactive ingredients:

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

Paxtine tablets do not contain sucrose, lactose, gluten or tartrazine.

### Manufacturer

Paxtine is made in Australia by:

**Alphapharm Pty Limited**

(ABN 93 002 359 739)

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Australian Registration Number:

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