

Paxtine

contains the active ingredient 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 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, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What is Paxtine used for

Paxtine is used to treat:

- major depression and prevent the return of depressive symptoms
- obsessive compulsive disorder (OCD) and prevent its recurrence
- panic disorders (panic attacks) and prevent its recurrence
- social anxiety disorder/social phobia
- general anxiety disorder (GAD)
- post-traumatic stress disorder (PTSD).

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

Your doctor may have prescribed Paxtine for another reason.

Paxtine is available only with a doctor's prescription.

Paxtine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by acting on chemicals in the brain called amines, which are involved in controlling mood.

Paxtine corrects this chemical imbalance and helps to relieve the symptoms of the above conditions.

Depression is a disorder where 'low moods' or feelings of sadness last longer, or are more severe than those that everyone has from time to time.

Depression is thought to be caused by a chemical imbalance in certain parts of the brain.

This imbalance affects your whole body and can cause emotional and physical symptoms such as low spirit, loss of interest in usual activities, changes in appetite, trouble sleeping, low energy and feeling guilty for no reason.

Obsessive compulsive disorder (OCD) is a condition where a person may have an irrational fear or obsessional behaviour which is repetitive and persistent. The symptoms of OCD vary from person to person.

Panic disorder is characterised by recurrent brief episodes of distress, confusion and fear, which may cause sweating, difficulty breathing or a fast and pounding heart beat.

Social anxiety disorder or social phobia causes people to fear and/or avoid social situations.

In general anxiety disorder (GAD), people experience excessive anxiety and worrying. Symptoms include

irritability, restlessness and/or tense muscles.

Post-traumatic stress disorder (PTSD) is a condition that causes people to have repetitive and distressing recollections of past traumatic events.

USE IN CHILDREN AND ADOLESCENTS

Paxtine is not recommended for use in children and adolescents below 18 years of age, as the drug has not been shown to be effective in this age group and there could be unwanted side effects (See While you are taking Paxtine - Things you must do).

Before you take Paxtine

When you must not take it

Do not take Paxtine if you are pregnant or plan 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.

There have also been reports of some babies experiencing complications immediately after delivery.

Do not take Paxtine if you are allergic to paroxetine (e.g. Aropax) or any of the ingredients listed at the end of this leaflet.

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.

Do not take Paxtine if you are currently taking a monoamine oxidase inhibitor (MAOI), or have taken one within the last 14 days.

Taking Paxtine with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Examples of MAOIs are phenelzine (Nardil), tranylcypromine (Parnate), moclobemide (eg. Aurorix, Arima), selegiline (Selgene, Eldepryl), and linezolid (Zyvox).

Do not take Paxtine if you are currently 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 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 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 any other medicines, foods, dyes or preservatives.

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

Paxtine is not recommended for use while breastfeeding, as it passes into breast milk and may affect your baby. Your doctor will have more information on the possible risks and benefits of taking Paxtine while breastfeeding.

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

- kidney problems
- liver problems
- heart problems
- bleeding problems
- epilepsy or seizures
- any other type of mental or emotional disorder such as mania or bipolar disorder, or a history of suicidal behaviour or thoughts
- glaucoma (increased pressure in the eye).

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

Taking other medicines

Do not take Paxtine if you are taking:

- any monoamine oxidase inhibitor (MAOI) such as:
 - phenelzine (Nardil), tranylcypromine (Parnate) and moclobemide (eg. Aurorix, Arima), used to treat depression
 - selegiline (Eldepryl, Selgene), used to treat symptoms of Parkinson's disease
 - the antibiotic linezolid.

Wait at least 14 days after stopping your MAOI, before starting Paxtine.

- thioridazine (Aldazine, Melleril) and pimozone (Orap), medicines used to treat schizophrenia.

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

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

- medicines used to treat depression, anxiety, or schizophrenia including medicines you buy without a doctor's prescription such as tryptophan or St John's Wort (*hypericum perforatum*)
- atomoxetine (Strattera), a medicine used to treat Attention

Deficit Hyperactivity Disorder (ADHD), a type of behavioural disorder

- fentanyl, a medicine used in anaesthesia or to treat chronic pain
- medicines used to control epilepsy, such as carbamazepine (e.g. Teril, Tegretol), phenytoin (Dilantin), sodium valproate and (Valpro, Epilim)
- medicines used to relieve migraine attacks, such as sumatriptan (e.g. Imigran), naratriptan (Naramig), zolmitriptan (Zomig)
- tramadol, a medicine used to relieve moderate to severe pain
- medicines used to prevent blood clots such as warfarin (Coumadin, Marevan)
- certain medicines used to treat Parkinson's disease such as procyclidine (Kemadrin)
- medicines used to control a fast or irregular heart beat such as flecainide (Flecatag, Tambacor)
- metoprolol (e.g. Minax, Betaloc), a medicine used to treat high blood pressure and other heart conditions
- cimetidine (e.g. Magicul, Tagamet), a medicine used to treat reflux and ulcers
- medicines used to treat HIV infection (fosamprenavir, ritonavir)
- tamoxifen, a medicine used to treat breast cancer
- Non-steroidal anti-inflammatory drugs (NSAID's), such as aspirin, which are used to treat both pain and inflammation.

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.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

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

How to take Paxtine

Follow all directions given to you by your doctor and 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.

How much to take

The dose varies from person to person.

Your doctor will decide the right dose for you. This may depend on your condition and how you respond to Paxtine.

The recommended dose of Paxtine is one tablet (20 mg) per day for:

- depression
- general anxiety disorder
- social anxiety disorder/social phobia
- post-traumatic stress disorder.

Your doctor may gradually increase this dose, usually over several weeks, depending on your response to Paxtine.

The recommended dose of Paxtine is two tablets (40 mg) per day for:

- obsessive compulsive disorder
- panic disorder.

However, your doctor may start you on a lower dose and increase the dose slowly over several weeks, depending on how you respond to Paxtine.

People with liver or kidney problems may require lower doses.

How to take it

Swallow the tablets with a glass of water.

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

Take Paxtine at about the same time each 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 Paxtine for as long as your doctor tells you to.

The length of treatment with Paxtine will depend on the condition you are being treated for and how quickly your symptoms improve.

Your doctor may decide that you should continue taking Paxtine for some time even when you have overcome your problem, to make sure the benefits last.

Most medicines of this type take time to work, so do not be discouraged if you do not feel better right away. While some symptoms will be relieved sooner than others, Paxtine usually takes a number of weeks before an improvement is really apparent.

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

Stopping Paxtine suddenly may increase your chances of getting unwanted side effects (see "Unwanted effects that may occur when treatment is stopped").

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

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.

If you take too much Paxtine you may experience nausea (feeling sick), vomiting, drowsiness, dizziness, confusion, agitation or irritability, sweating, have a fast heart beat, or lose consciousness.

While you are taking Paxtine

Things you must do

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

A worsening of depressive symptoms including thoughts of suicide or self-harm may occur during initial treatment (generally the first one to two months) or when the doctor changes your dose. These symptoms should be controlled when the full effect of Paxtine takes place.

Children, adolescents or young adults under 25 years of age are more likely to experience these effects during the first few months of treatment.

Patients and caregivers should be alert and monitor for these effects.

Contact your doctor or a mental health professional right away or

go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- any worsening of their condition
- 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 mood or behaviour.

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.

If you become pregnant or intend to become pregnant while taking Paxtine, tell your doctor immediately so your treatment can be reviewed.

It is important that you do not stop taking Paxtine suddenly as it can cause withdrawal side effects (see "Unwanted effects that may occur when treatment is stopped").

Talk to your doctor about any problems you may have and how you feel.

This is especially important if you have any feelings of severe sadness or thoughts of suicide, or if you experience any unusual bursts of energy or anger. Talking to your doctor will help him/her determine the best treatment for you.

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

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 stop taking Paxtine or change the dose, unless advised by your doctor.

Stopping Paxtine suddenly may cause a range of unwanted side effects (see "Unwanted effects that may occur when treatment is stopped")

When your doctor decides you no longer need Paxtine, your doctor will tell you how to gradually reduce the amount of Paxtine you are taking before stopping completely. This is usually done slowly over several weeks.

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 driving or operating machinery until you know how Paxtine affects you.

Paxtine may cause drowsiness, dizziness or lightheadedness in some people. Make sure you know how Paxtine affects you before you drive a car, operate machinery or do things that could be dangerous.

Be careful drinking alcohol while taking Paxtine.

Your doctor may suggest that you avoid alcohol while being treated with Paxtine.

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.

Side effects

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

Paxtine helps most people, but it may have unwanted side effects in some 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 this list of possible side effects.

You may not experience any of them.

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

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

- nausea
- vomiting
- dry mouth
- reduced appetite
- diarrhoea or constipation
- unusual tiredness or weakness
- dizziness, drowsiness, difficulty getting to sleep
- headache
- shaking or tremors
- sweating
- abnormal dreams (including nightmares)
- sexual problems.

The above list includes the more common and mild side effects of Paxtine.

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

- muscle pain or joint pain
- restlessness, difficulty sitting still
- stomach pain with nausea and vomiting, vomiting blood, blood in the bowel motions
- increased skin sensitivity to the sun with sunburn occurring more quickly than normal
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal.
- vaginal bleeding outside the usual cycle
- bleeding nose occurring more frequently than usual
- irresistible urge to move the legs (Restless Legs Syndrome).

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

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

- signs of an allergic reaction such as skin rash, itching or hives; shortness of breath, wheezing or trouble breathing; swelling of the face, lips, tongue or other parts of the body
- chest pain, or a fast or irregular heart beat
- sudden or unpredicted changes in mood or thinking
- sudden fever, hallucinations, loss of coordination, confusion and overactive reflexes
- sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- fits or seizures.

The side effects listed above are rare but very serious, and require urgent medical attention or hospitalisation.

Although Paxtine is not recommended for use in children and adolescents below 18 years of age, the most common side effects reported in studies with this age group were:

- 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.

Unwanted effects that may occur when treatment is stopped:

- dizziness
- pins and needles, burning sensations or electric shock sensations
- buzzing or ringing in the ears

- sleep disturbances such as intense dreams
- agitation or anxiety
- nausea (feeling sick) or diarrhoea
- shaking or tremors
- confusion
- headache
- sweating.

The above symptoms are likely to occur during the few first few days of stopping treatment but usually disappear within a few weeks. They may also occur very rarely if you miss a dose. See your doctor if they are severe or persistent.

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

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

After taking Paxtine

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 30°C.

If stored under these conditions, the tablet can last for up to 2 years.

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.

Product description

What it looks like

Paxtine is a white, film-coated oval-shaped biconvex tablet with a breakline on one side and marked "20" on the other side.

Each pack contains 30 tablets.

Ingredients

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

Each Paxtine tablet contains 20 mg of paroxetine.

The tablets also contain the following inactive ingredients:

- titanium dioxide (E171)
- calcium hydrogen phosphate
- hypromellose
- sodium starch glycollate
- magnesium stearate
- polysorbate 80
- macrogol 400.

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

Supplier

Paxtine is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian Registration Number:

AUST R 80956

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