

## APO-Paroxetine Tablets

Paroxetine hydrochloride

### Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

#### What is in this leaflet

This leaflet answers some common questions about paroxetine. 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 using this medicine 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 this medicine is used for

Paroxetine is used to treat:

- depression
- Obsessive Compulsive Disorder (OCD)
- panic disorder
- social anxiety disorder or social phobia
- generalised anxiety disorder
- post-traumatic stress disorder.

It is also used to prevent the symptoms of depression, Obsessive Compulsive Disorder and panic disorder from coming back.

Paroxetine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

#### How it works

Paroxetine is thought to work by acting on brain chemicals called amines which are involved in controlling mood. Paroxetine corrects the chemical imbalance and helps to relieve the symptoms of depression and stop them coming back.

Depression is longer lasting and/or more severe than the 'low moods' everyone has from time to time due to the stress of everyday life. 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, not interested in usual activities, being unable to enjoy life, poor appetite or overeat, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

Paroxetine is thought to have a similar action when it is used to for irrational fears, obsessional behaviour or panic attacks, and when it is used to treat patients who may avoid or are fearful of social situations, have excessive anxiety and worry, who feel irritable, restless and/or tense in the muscles, or who experience repeated and distressing recollections of a past traumatic event.

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

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive

Paroxetine is not recommended for use in children under 18 years of age. It has been shown that the risk of serious side effects such as suicidal thoughts and actions is higher in this age group.

#### Before you take this medicine

##### When you must not take it

**Do not take this medicine if you have an allergy to:**

- 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, throat or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you are taking other medicines called Monoamine Oxidase Inhibitors (MAOIs).**

MAOIs may be used for the treatment of depression (e.g. phenelzine, tranylcypromine, moclobemide), Parkinson's disease (e.g. selegiline), infections (e.g. linezolid), or diagnosis of certain conditions or treatment of certain blood disorders (e.g. methylene blue). Check with your doctor or pharmacist if you are taking any MAOIs.

**Do not take paroxetine until 14 days after stopping any MAOI, and do not take MAOIs until 14 days after stopping paroxetine.**

Taking paroxetine with or within 14 days of taking MAOIs may cause a serious reaction with a sudden increase in body temperature, very high blood pressure and convulsions. Your doctor will know when it is safe to start paroxetine after the MAOI has been stopped.

**Do not take this medicine if you are taking thioridazine or pimozide for the treatment of schizophrenia or other psychoses (disturbances in thinking, feelings and behaviours).**

**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 have allergies to any other medicines, foods, preservatives or dyes.**

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

- mania, hypomania, bipolar disorder, previous episodes of depression or other psychiatric conditions
- epilepsy, fits or seizures
- heart, liver or kidney problems
- narrow-angle glaucoma (raised pressure in the eye)
- problems with blood clotting or abnormal bleeding
- diabetes
- thoughts or actions relating to self-harm or suicide
- intolerance to lactose. These tablets contain lactose.

**Tell your doctor 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 heart defects in babies. If you become pregnant or intend to become pregnant while taking this medicine, see your doctor for a review of your treatment immediately. It is important that you do not stop taking this medicine suddenly. Paroxetine can have withdrawal side effects if stopped suddenly.

**If you are male, your chances of fathering a child may be reduced.**

**Tell your doctor if you are breastfeeding.**

Paroxetine passes into breast milk and it is not known if it affects babies. Your doctor will 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 this medicine.**

##### Taking other medicines

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

When taken with paroxetine, some medicines may increase the risk of having serious side effects. These serious side effects may be lifethreatening. These include:

- MAOIs (e.g. phenelzine, tranylcypromine, moclobemide, linezolid, selegiline, methylene blue)
- thioridazine and pimozide.

Other medicines may interfere with paroxetine. These include:

- tricyclic antidepressants (e.g. nortriptyline, amitriptyline, imipramine, desipramine)
- other SSRIs (e.g. fluoxetine, citalopram, sertraline, fluvoxamine)
- medicines used for treating disorders which affect the way you think, feel or act (e.g. perphenazine, risperidone, atomoxetine, lithium)
- procyclidine, selegiline used to treat Parkinson's disease
- some medicines used to control epilepsy or fits (e.g. phenytoin, carbamazepine, phenobarbital, sodium valproate)
- metoprolol and flecainide, used to lower blood pressure or treat heart conditions
- aspirin, non-steroidal antiinflammatory drugs (NSAIDs) and anti-coagulants (such as warfarin), which can thin the blood
- cimetidine, used to treat stomach ulcers or reflux
- some medicines used to treat migraines (e.g. sumatriptan, naratriptan, zolmitriptan)
- St John's Wort (*Hypericum perforatum*) or L-tryptophan, contained in some multivitamin and herbal preparations
- medicines used to relieve severe pain (e.g. fentanyl, tramadol)
- tamoxifen, used to treat breast cancer
- fosamprenavir and ritonavir, used to treat HIV infection
- anaesthetic medicines (e.g. mivacurium, suxamethonium).

These medicines may be affected by this medicine 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.

Other medicines not listed above may also interact with paroxetine.

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## How to take this medicine

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

They may differ to the information contained in this leaflet.

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

### *How much to take*

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

If you have kidney or liver problems, then the doses may be lower.

**For depression, social anxiety disorder/social phobia, generalised anxiety disorder or post-traumatic stress disorder:**

The usual dose is one 20 mg tablet taken once a day. This dose may be increased slowly by your doctor if needed. This may require you to break the tablet in half. The dose should not go above 50 mg per day in adults, or 40 mg per day in elderly people.

**For obsessions and compulsions or panic attacks:**

The usual dose is two 20 mg tablets taken once a day. Your doctor should start you on a lower dose and increase the dose slowly over several weeks. This may require you to break the tablet in half. The dose should not go above 60 mg per day in adults, or 40 mg per day in elderly people.

### *How to take it*

**Swallow the tablets with a glass of water.**

The tablets should not be chewed.

### *When to take it*

**Take this medicine in the morning at about the same time each day.**

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

It should preferably be taken with food.

### *How long to take it for*

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

Make sure you have enough to last over weekends and holidays.

Like other drugs of this type, this medicine 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 your medicine starts to work.

**Make sure that you or anyone close to you or caring for you watch for these symptoms in the first few months of treatment or when changing the dose. 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.**

**Contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.**

## Stopping Treatment

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

Your doctor may decide that you should continue to take it for some time, even when you have overcome your problem. For best effect, this medicine must be taken regularly.

Your doctor will tell you when and how this medicine 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 this medicine, especially if this is done suddenly, you may experience unwanted side effects such as feeling dizzy, sick or anxious; sweating; pins and needles or electric shock feelings, or disturbed sleep.

### *Use in children and adolescents*

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

The use of Paroxetine 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 Paroxetine, 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.

### *Use in Pregnancy*

If you take paroxetine 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 paroxetine so they can advise you.

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*

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

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of unwanted side effects.

**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 your nearest hospital, if you think that you or anyone else may have taken**

**too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, tremor, dilated pupils, dry mouth, sedation, sweating, dizziness, confusion, headache, fast heartbeat and irritability.

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## While you are taking this medicine

### *Things you must do*

**People taking paroxetine may be more likely to think about killing themselves or actually try to do so, especially when paroxetine is first started or the dose is changed.**

**Tell your doctor immediately if you have thoughts about killing yourself, or if you are close to or care for someone using paroxetine who talks about or shows signs of killing him or herself.**

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

**If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking paroxetine, contact a doctor immediately, or even to go to the nearest hospital for treatment:**

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

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

**Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are a male and you and your partner have been unsuccessful whilst trying for a baby, tell your doctor.**

Some studies have shown that medicines such as paroxetine may affect sperm quality. However, the effect goes away if the medicine is stopped.

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

**If you have an accident, and/or break a bone, tell your doctor that you are taking paroxetine.**

Some antidepressant medicines have been associated with an increased risk of bone fracture.

**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 effective 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, thoughts of suicide, bursts of unusual energy, anger or aggression, or if you become particularly agitated or restless.

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

### *Things you must not do*

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

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how this medicine affects you.**

This medicine may cause dizziness, drowsiness, light-headedness or problems concentrating in some people. If you have any of these symptoms, do not drive a car; operate machinery, or anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking paroxetine.**

If you drink alcohol, dizziness, drowsiness or impaired concentration may be worse, or your symptoms of depression or anxiety may become worse. Your doctor may suggest avoiding alcohol while you are being treated with this medicine.

There is an increased risk of breaking a bone in people taking medicines like paroxetine. This risk is greatest during the early stages of treatment.

**You should wait at least 14 days after stopping paroxetine before starting any medicines known as monoamine oxidase inhibitors (MAOIs), such as phenelzine, tranylcypromine and moclobemide.**

**When your doctor decides that you should stop taking this medicine, the dose may be reduced slowly or the time between the doses increased over 1 to 2 weeks (see 'Stopping Treatment').**

**Although paroxetine 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

**Tell your doctor as soon as possible if you do not feel well while you are taking paroxetine.**

This medicine helps most people, 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Do not be alarmed by the following lists 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 or pharmacist if you notice any of the following and they worry you:**

- gastrointestinal problems e.g. feeling or being sick, dry mouth, increased or decreased appetite, wind, indigestion, constipation or diarrhoea
- vomiting
- drowsiness, dizziness, difficulty in getting to sleep;
- impaired sexual function
- weakness
- feeling sweating or shaky

- bruising
- abnormal dreams (including nightmares)
- weight gain or loss

The above list includes the more common side effects of your medicine.

### **MORE SERIOUS EFFECTS**

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

- muscle spasms or twitches, facial twitching, feeling restless and needing to move often
- **Stop taking paroxetine and contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:**
  - shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (symptoms of an allergic reaction).
  - severe 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) (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 increase in body temperature, severe convulsions (fits)
  - fast heartbeat, sweating, muscle spasm, racing thoughts, restlessness.

**Other rare events that have been reported with paroxetine include:**

- blurred vision
- abnormal liver function
- low levels of sodium in the blood, especially in older people
- 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).
- Restless Legs Syndrome (leg discomfort in the calves, twitching, burning, tingling, feeling of insects crawling)
- menstrual period disorder (including heavy periods, bleeding between periods and absence of periods)
- heavy vaginal bleeding shortly after birth
- severe allergic reactions.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

### *Withdrawal Symptoms*

**Unwanted effects that may occur after paroxetine has been stopped suddenly include:**

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

- disturbed sleep (including nightmares)
- tinnitus (ringing or buzzing in the ears)
- confusion

These are likely to occur within 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 paroxetine too quickly.

Therefore, always consult your doctor before stopping your medicine.

For most people, the above side effects will disappear within a few weeks. However, if you feel that these effects are too severe, see your doctor who can suggest how to stop your medicine more gradually.

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 paroxetine is not recommended for children under 18 years of age, the most common unwanted effects in this age group are as follows:**

- decreased appetite
- uncontrollable trembling or shaking
- sweating
- hyperactivity
- abdominal (e.g. stomach) pain
- hostile or unfriendly behaviour
- trying to harm themselves
- thinking about or trying to commit suicide
- changing emotions or moods e.g. feeling tearful
- feeling nervous or agitated.

**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 patients.

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## Storage and Disposal

### *Storage*

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

If you take your medicine out of the pack it may not keep well.

**Keep your medicine in a cool, dry place where the temperature stays below 25°C. Protect from moisture.**

**Do not store your medicine 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 this medicine 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.

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## Product description

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### *What it looks like*

#### **20 mg tablets:**

White, oval, biconvex and film-coated, with a partial bisect and engraved "20" on one side. The other side is plain.

Blister pack of 30 tablets.

AUST R 150212

### *Ingredients*

Each tablet contains 20 mg of paroxetine hydrochloride as the active ingredient.

It also contains the following:

- magnesium stearate
- sodium starch glycollate
- lactose
- hydroxypropylcellulose
- hypromellose
- macrogol 8000
- titanium dioxide.

This medicine does not contain gluten, sucrose, tartrazine and other azo dyes.

### *Sponsor*

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113

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This leaflet was prepared in July 2021.