

# **APO-Paroxetine Tablets**

Contains the active ingredient paroxetine (as paroxetine hydrochloride)

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## **Consumer Medicine Information**

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

## **What is in this leaflet**

**Read this leaflet carefully before taking your medicine.**

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on the medicine may be available.

### **Ask your doctor or pharmacist:**

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or

- to obtain the most up-to-date information

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

## **What this medicine is used for**

The name of your medicine is APO-Paroxetine. It contains the active ingredient, paroxetine (as paroxetine hydrochloride).

It 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.

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.

## **How it works**

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

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 such as feeling low in spirit, not interested in usual 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. Paroxetine corrects the chemical imbalance and so helps to relieve the symptoms of depression, and stops them coming back.

Paroxetine is thought to have a similar action when it used to treat or prevent irrational fears or obsessional behaviour or panic attacks, and when it is used to treat patients who may avoid and/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.

There is no evidence that this medicine is addictive

Clinical experience has shown that paroxetine should not affect the ability to drive or operate machinery. However, make sure you know how paroxetine affects you before driving or operating machinery, as it can make some people drowsy or dizzy or affect their concentration.

## **Use in children**

Paroxetine is not recommended for use in anyone 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 people under 18.

## **Before you take this medicine**

### **When you must not take it**

**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 (phenelzine, tranylcypromine, moclobemide), Parkinson's disease (selegiline) infections (linezolid), or diagnosis of certain conditions / treatment of certain blood disorders (methylene blue).**

There may be others MAOIs also so check with your doctor or pharmacist.

**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.

- **You are taking thioridazine or pimozide for the treatment of schizophrenia or other psychoses (disturbances in thinking, feelings and behaviours).**
- **You have had an allergic reaction to paroxetine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include cough, 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, fainting or hayfever-like symptoms.

**If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

## **Before you start to take it**

**Before you start taking this medicine, tell your doctor if:**

**1. You have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes.

**2. You have or have had any medical conditions, especially the following:**

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

- 3. You are receiving electro-convulsive therapy (ECT).**
- 4. You should not take this medicine if you are pregnant or intend to become pregnant, unless your doctor thinks it is necessary, however you must not stop taking this medicine suddenly.**

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, you should make an appointment to see your doctor and have your treatment reviewed.

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.

- 5. You are breast-feeding or planning to breast-feed.**

Paroxetine passes into breast milk. It is not known if it affects babies, so discuss with your doctor the risks and benefits of taking this medicine whilst breast-feeding.

- 6. You are planning to have surgery.**
- 7. You are currently receiving or are planning to receive dental treatment.**
- 8. You are taking or are planning to take any other medicines.**

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

**Some combinations of medicines may increase the risk of having serious side effects. These serious side effects may be life-threatening.**

- **Monoamine oxidase inhibitors (MAOIs), which include phenelzine, tranylcypromine, moclobemide, linezolid, selegiline and methylene blue.**
- **Thioridazine and pimozide.**

Other medicines may interact with paroxetine, these include:

- tricyclic antidepressants, such as nortriptyline, amitriptyline, imipramine and desipramine
- other SSRIs (fluoxetine, citalopram, sertraline, fluvoxamine)
- lithium
- perphenazine, risperidone or atomoxetine, medicines used for treating disorders which affect the way you think, feel or act
- procyclidine, used to treat Parkinson's disease
- fentanyl, used to relieve severe pain
- phenytoin, carbamazepine, phenobarbital and sodium valproate, used to control epilepsy or fits.



- metoprolol and flecainide, which lower blood pressure or treat heart conditions
- aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) and anti-coagulants (such as warfarin), which can thin the blood
- cimetidine, used to treat stomach ulcers or reflux
- a class of medicines used to treat migraines called triptans, examples include sumatriptan, naratriptan and zolmitriptan
- St John's Wort (*Hypericum perforatum*) or tryptophan, contained in some multivitamin and herbal preparations, which can be bought without a prescription
- tramadol, a strong pain-killer
- tamoxifen, used to treat breast cancer
- fosamprenavir and ritonavir, used to treat HIV infection
- L-tryptophan.
- Medicines used in anaesthesia, such as mivacurium and suxamethonium.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with paroxetine.

## **How to take this medicine**

Follow carefully all directions given to you by your doctor or pharmacist carefully. Their instructions may be different to the information in this leaflet.

## **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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

The usual dose of paroxetine for depression, social anxiety disorder/social phobia, generalised anxiety disorder or post-traumatic stress disorder is one 20 mg tablet taken once each day. If 20 mg is not working, your doctor may increase the dose slowly by adding 10 mg at a time. The dose should not go above 50 mg per day in adults, or 40 mg per day in elderly people.

The usual dose of paroxetine for obsessions and compulsions or panic attacks is two 20 mg tablets taken once each day. Your doctor should start you on a lower dose and increase the dose slowly by adding 10 mg at a time 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.

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

## **How to take it**

Swallow the tablets with a glass of water.

The tablets should not be chewed.

## **When to take it**

Take your medicine in the morning, preferably with food.

Take this medicine at 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.

## **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 or**

**treatment or when changing the dose, and that you or your carer 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 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.

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

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

**Do not take a double dose to make up for missed doses.**

This may increase the chance of unwanted side effects.

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

## **If you take too much (overdose)**

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**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.

## **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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed
- you are about to have any blood tests
- you are going to have surgery.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

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.

**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, be sure to 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 their symptoms seem similar to yours
- take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- stop taking your medicine suddenly, or change the dosage, without first checking with your doctor.

## **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.

**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.

Some people may have symptoms such as such as feeling dizzy, sick or anxious; sweating; pins and needles or electric shock feelings, or disturbed sleep if paroxetine is stopped, particularly if stopped suddenly.

## **Possible side effects**

Tell your doctor as soon as possible if you do not feel well while you are taking paroxetine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

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

This list includes mainly the more common side effects.

- feeling or being sick, dry mouth, increased or decreased appetite, wind, indigestion, constipation or diarrhoea,

problems with your mouth, throat gums, tongue, lips or teeth, teeth grinding

- yeast infection of the mouth
- sleepiness, dizziness, giddiness, difficulty in getting to sleep; strange dreams
- feeling nervous or anxious or agitated
- sexual problems
- pain, weakness or apathy
- chills, fever or feeling sweaty or shaky
- mild rash, itching, excess sweating
- sunburn-type rash following a short time in the sun
- red bumps on the shins, rash following skin contact with certain types of materials
- impaired concentration, confusion
- strange taste or lack of taste sensation
- frequent or painful urination or large amounts of urine produced, night time urination
- headache
- weight gain or loss

- muscle weakness or muscle or joint or cartilage pain or inflammation
- stiff or painful neck
- burping or problems swallowing
- sore throat, yawning, cough, stuffy nose
- excess saliva
- breast pain, missed or painful periods
- acne, hair loss or excess growth, dry skin, unusual bruising, eczema, boils, cold sores

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

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

- muscle spasms or twitches, facial twitching, feeling restless and needing to move often
- 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)
- abnormal bleeding (including vaginal and gastrointestinal bleeding, nosebleed) or bruising, bloody diarrhoea, black tarry stools, vomiting blood

- confusion, changing emotions or mood
- low levels of sodium in the blood, especially if you are over 65 years of age.

This may be felt as sleepiness and muscle weakness.

- feeling dizzy or faint when standing up (due to low blood pressure)
- high or low blood pressure
- flushing
- pain in the upper or lower abdomen
- varicose veins, swollen veins
- migraine or severe headache
- shingles (painful skin rash with blisters), discoloured or ulcerated skin
- abnormal breast milk production, infected breasts
- problems with your eyes or eyesight
- problems with your ears or hearing
- problems with urinating (pain, burning, too little or too much or too often or not often enough)
- vaginal irritation or infection
- diabetes or thyroid problems

- changes in your blood which you may notice as feeling tired, weak, thirsty, easily bruised, or prone to infections
- yellowing of your skin or eyes. unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate liver problems)

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects .You may need urgent medical attention or hospitalisation.

- sudden increase in body temperature, severe convulsions (fits)
- sudden fever, hallucinations, loss of coordination, confusion and overactive reflexes
- fast heartbeat, sweating, muscle spasm, racing thoughts, restlessness
- thumping, fluttering, slow or irregular heartbeat, chest pain or left arm/neck pain, unconsciousness
- blood clots, swollen veins due to blood clots, coughing up blood
- thinking or acting strangely

- mood of excitement, over-activity and uninhibited behaviour
- thoughts of suicide and attempting suicide or self-harm
- sudden weakness or numbness of the face, arms or legs, especially on one side, slurred speech
- suddenly getting long-lasting muscle spasms, affecting the eyes, head, neck and body.
- feeling out of sorts, with fever, headache and cough, then suddenly getting spots or blisters which quickly develop into large amounts of blistering or peeling skin
- kidney stones and/or kidney pain, blood in the urine.

## **Allergic reactions**

**If you think you are having an allergic reaction to paroxetine, stop taking this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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

- fainting
- hayfever-like symptoms

## **Withdrawal Symptoms**

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

- dizziness
- sensory disturbances such as, pins and needles, burning sensations and electric shock-like sensations
- feeling sick
- agitation or anxiety
- sweating, shaking or tremors
- confusion
- disturbed sleep (including nightmares)
- tinnitus (ringing or buzzing in the ears)
- headache
- diarrhoea.

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 look at phasing out your medicine more gradually.

**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.

The list above does not include every side effect seen with paroxetine.

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



# Storage and Disposal

## Storage

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool, dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

## Product description

### What APO-Paroxetine Tablet 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

### Ingredients

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

It also contains the following inactive ingredients:

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

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

## **Australian Registration Number**

### **APO-Paroxetine 20 mg tablets:**

AUST R 150212

## **Sponsor**

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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