

# APO-PAROXETINE TABLETS

Paroxetine hydrochloride (20mg)

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## What Apo-Paroxetine is used for

Apo-Paroxetine has been prescribed to you by your doctor to relieve your symptoms of the following conditions:

- depression
- panic disorder, with or without agoraphobia (fear of public or open spaces)
- obsessive-compulsive disorder (OCD) (persistent, obsessive thoughts that make you carry out repetitive behaviour)

## How Apo-Paroxetine works

Apo-Paroxetine contains the active ingredient paroxetine. It belongs to a family of medicines called Selective Serotonin Reuptake Inhibitors (SSRIs). Apo-Paroxetine is believed to work by enhancing the availability of serotonin, one of the chemical substances in the brain. Depression and OCD have been associated with a decrease in the flow of serotonin between certain brain cells.

## Before you use Apo-Paroxetine

### - When you must not use it

Do not use Apo-Paroxetine if you are allergic to paroxetine hydrochloride or any other ingredients in this medication (See section **Product Description**).

Do not take Apo-Paroxetine if you are taking or have recently taken medicines called monoamine oxidase inhibitors (MAOIs) within the last 14 days.

Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI. Your doctor will know when it is safe to start Apo-Paroxetine after the MAOI has been

stopped, or to start another MAOI after discontinuing Apo-Paroxetine treatment.

Do not take Apo-Paroxetine if you are taking thioridazine or pimozide (medicines used for mental disorder)

### - Before you start to use it

Before taking Apo-Paroxetine, your doctor needs to know any other medical condition that you may have including:

- heart or liver disease
- a history of seizures (fits)
- glaucoma (high pressure within the eye)
- bleeding problems
- electroconvulsive therapy (ECT), generally used for severe depression or other mental illnesses
- hyponatremia (low sodium level)
- severe kidney impairment
- age (paediatric or elderly)

### *Pregnancy and lactation*

Paroxetine should only be used during pregnancy when strictly indicated. Ask your doctor or pharmacist for advice before taking any medicine.

If you take Apo-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 should be aware that you are taking Apo-Paroxetine so they can advise you.

### - Taking other medicines

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 medications may interfere with Apo-Paroxetine, which includes:

- MAOI medications (View subsection "*When must you not use it*")
- Serotonergic medications
- Other medicines for depression, such as tricyclic antidepressants (TCAs; e.g. clomipramine and nortriptyline)
- Medicines used to treat mental illness, such as lithium

- Medicines used to treat seizures (fits), such as phenytoin and carbamazepine
- Medicines used to treat Parkinson's disease, such as procycline
- Blood-thinning medicines or medicines with bleeding risks, such as warfarin and aspirin, and nonsteroidal anti-inflammatory drugs (NSAID)
- Medicines used to treat heart conditions such as propafenone and flecainide
- Pravastatin (for cholesterol treatment)

## How to use Apo-Paroxetine

### - How much to use

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 label, ask your doctor or pharmacist for help.

### *Depression*

*Usual adult dose:* The administration of Apo-Paroxetine (paroxetine) should be initiated at 20 mg daily. For most people, 20 mg daily will also be the optimum dose.

*Dose range:* If you do not respond adequately to the 20 mg daily dose, a gradual increase in dosage up to 40mg daily may be considered by your doctor. The maximum recommended daily dose is 50 mg.

### *Obsessive-compulsive disorder (OCD)*

*Usual adult dose:* The administration of Apo-Paroxetine (paroxetine) should be initiated at 20 mg/day. The recommended dose of Apo-Paroxetine in the treatment of OCD is 40 mg daily.

*Dose range:* If you do not respond adequately to the 40 mg daily dose, a gradual increase in dosage may be considered by your doctor. The maximum recommended daily dose is 50 mg.

### *Panic Disorder*

Usual adult dose: The recommended starting dose of Apo-Paroxetine (paroxetine) in the treatment of panic disorder is 10 mg/day. The recommended dose of Apo-Paroxetine in the treatment of panic disorder is 40 mg/daily.

*Dose range:* If you do not respond adequately to the 40 mg daily dose, a gradual increase in dosage may be considered by your doctor. The maximum recommended daily dose is 60 mg.

### **Elderly**

The recommended initial dose is 20 mg/day for elderly and/or debilitated people. The dose may be increased if indicated up to a maximum of 40 mg daily.

### **Renal/Hepatic Impairment**

Apo-Paroxetine should be used with caution in people with kidney or liver impairment. The recommended initial dose is 20 mg/day in patients with clinically significant kidney or liver impairment. A maximum dose of 40 mg should not be exceeded.

### **Children and adolescent**

Apo-Paroxetine is not recommended for children and adolescents less than 18 years.

#### **- When to use it**

Use as directed by your doctor or pharmacist.

#### **- How long to use it**

Continue taking Apo-Paroxetine for as long as your doctor recommends.

#### **- If you forget to use it**

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

#### **- If you use too much (overdose)**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think 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.

If you take too much of this medication, you might experience some symptoms mentioned under 'Side effects'.

In the event that you are taking other psychotropic medications, there is a possibility that you might experience heartbeat changes or coma, if you take both these medications and overdose on Paroxetine.

### **While you are using it**

Medicines like Apo-Paroxetine (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.

#### **- Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Apo-Paroxetine.

Tell your doctor immediately if you become pregnant while taking this medication.

#### **- Things you must not do**

Do not stop taking the medicine unless advised by your doctor.

Your doctor may want you to gradually reduce the amount of Apo-Paroxetine you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms (such as dizziness, paresthesia [tingling sensation], headache, nausea and anxiety)

Do not take any new medicines without consulting your doctor.

Do not give Apo-Paroxetine to anyone else, even if they have the same symptoms or condition as you.

#### **- Things to be careful of**

### ***Driving and using machines***

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

### ***Suicidality in Children and Adolescent***

Apo-Paroxetine increases the risk of suicidal ideation and behavior in children. Despite this, your doctor may prescribe Apo-Paroxetine for you or your child when he/she decides that this is in their best interests.

If your doctor has prescribed Apo-Paroxetine for a child under 18 and you want to discuss this, please go back to your doctor. Families or caregivers should pay close attention to your child whenever Apo-Paroxetine is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in you or your child's behavior.

### **Side effects**

Like all medicines, Apo-Paroxetine can cause side effects, although not everybody gets them.

### **Side effects might include:**

Blood and lymphatic system disorders: abnormal bleeding, thrombocytopenia (low platelet count).

Immune system disorders: severe allergic reactions.

Endocrine disorders: syndrome of inappropriate anti-diuretic hormone secretion. (SIADH)

Metabolism & nutrition disorders: increases cholesterol level, decreased appetite, altered blood sugar control, hyponatraemia (low sodium level in blood).

Psychiatric disorder: somnolence (sleepiness), insomnia (sleeping difficulties), agitation, confusion, hallucinations (hearing voices or seeing things which are not there), manic

reactions (unusual behaviour caused by uncontrollable excitement), anxiety, suicidal ideation.

Nervous system disorders: dizziness, tremor, convulsions, serotonin syndrome (symptoms may include agitation, confusion, diaphoresis (excessive sweating), hallucinations, hyperreflexia (overresponsive reflexes), myoclonus (muscle twitching), shivering, tachycardia (rapid heart beat) and tremor).

Eye disorders: blurred vision, enlargement of pupil, acute glaucoma.

Ear and labyrinth disorders: Internal sound continuous in the ear

Cardiac disorders: rapid heartbeat, slow heartbeat.

Vascular disorders: transient increases or decreases in blood pressure.

Respiratory, thoracic and mediastinal disorders: yawning.

Gastrointestinal disorders: nausea, constipation, diarrhoea, dry mouth, gastrointestinal bleeding.

Hepato-biliary disorders: elevation of liver enzymes, liver events (such as hepatitis, sometimes associated with jaundice and/or liver failure).

Skin & subcutaneous tissue disorders: sweating, skin rashes, itching, blister, photosensitivity reactions, severe skin allergic reaction with painful red rashes and blister

Renal & urinary disorder: urinary retention and incontinence

Reproductive system & breast disorders: sexual dysfunction, hyperprolactinaemia/galactorrhoea (milky nipple discharge unrelated to the normal milk production of breast-feeding), priapism (persistent and often painful erection), menstrual disorder.

Musculoskeletal disorders: arthralgia (joint pain), myalgia (muscle pain).

General disorders and administration site conditions: asthenia (weakness), body weight gain, peripheral oedema (fluid retention).

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of Apo-Paroxetine**

- Storage  
Keep out of the reach and sight of children.

Store below 30°C. Protect from moisture.

- Disposal  
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like  
Apo-Paroxetine should be pink, oval-shaped, biconvex, film-coated tablet. Scored and engraved 20 on one side, APO on the other side.

- Ingredients

- Active ingredient Paroxetine hydrochloride
- Inactive ingredients Magnesium stearate, sodium starch glycolate, anhydrous lactose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, D&C Red #30 Aluminium Lake, purified water.

- MAL number(s):  
MAL06091376AZ

**Manufacturer**  
Apotex Inc.  
150 Signet Drive  
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**Product Registration Holder**  
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