

HOVID PAROXETINE TABLET

Paroxetine Hydrochloride Hemihydrate (20 mg)

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What Paroxetine is used for

Paroxetine is used to treat:

- Depression
- Obsessive-compulsive disorder (repetitive, obsessive thoughts with uncontrollable behavior)
- Panic disorder with and without agoraphobia (fear of public and open spaces)
- Social anxiety or social phobia (fear or avoidance of social situations)
- Generalised anxiety disorder (generally feeling very anxious or nervous)
- Post-traumatic stress disorder (anxiety caused by a traumatic event)

How Paroxetine works

This medicine belongs to a group known as selective serotonin reuptake inhibitor (SSRI) antidepressants, which act by inhibiting the neuronal uptake of serotonin in the central nervous system, thereby relieving the symptoms of depression. Serotonin is one of several brain chemicals called amines which are involved in controlling mood.

Before you use Paroxetine

- When you must not use it

Do not take this medicine if:

- you are allergic to paroxetine or any of the ingredients listed at the end of this leaflet.
- you are taking another medicine for depression called monoamine oxidase inhibitor (MAOI), or have

taken a MAOI within the last 14 days.

- you are taking thioridazine, a medicine to treat disturbances in thinking, feelings and behavior (schizophrenia).

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

- Before you start to use it

Tell your doctor/pharmacist if:

- you are pregnant or plan to become pregnant
- you are breastfeeding
- you have raised pressure in the eye
- you have problems with your heart, kidney or liver.
- you have problems with blood clotting
- you suffer from epilepsy or have had a fit in the past.
- you have other psychiatric conditions

- Taking other medicines

Paroxetine may affect or be affected by other medicines you are taking. Talk to your doctor or pharmacist if you are taking any other medicines in any forms including any that you buy or obtain without a prescription.

They include:

- other antidepressant medicines known as MAOIs, SSRIs and tricyclic antidepressants (TCAs)
- lithium
- medicine used to relieve anxiety
- medicine used to treat psychosis (loss of contact with reality) (such as perphenazine)
- medicine used to control fits (such as phenytoin)
- medicine used to prevent blood clots (such as warfarin)
- medicine used to treat heart conditions (such as propafenone)
- medicine used to treat migraine (a recurrent, throbbing headache,

usually affecting only one side of the head)

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use 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.

Adults

Depression:

Oral, 20 mg daily. Dose may be increased slowly by 10 mg increments to a maximum of 50 mg daily according to individual responses.

Obsessive compulsive disorder:

Oral, 40 mg daily. Initial dose of 20 mg daily, may be increased weekly in 10 mg increments up to a maximum of 60 mg daily.

Panic disorder:

Oral, 40 mg daily. Initial dose of 10 mg daily, may be increased weekly in 10 mg increments up to a maximum of 50 mg daily.

Social anxiety disorder/ Social Phobia:

Oral, 20 mg daily. Dose may be increased weekly in 10 mg increments up to a maximum of 50 mg daily according to individual responses.

Generalized anxiety disorder:

Oral, 20 mg daily. Dose may be increased weekly in 10 mg increments up to a maximum of 50 mg daily according to individual responses.

Post-traumatic stress disorder:

Oral, 20 mg daily. Dose may be increased weekly in 10 mg increments up to a maximum of 50 mg daily according to individual responses.

Elderly

Dosing should begin with the adult dose and may be increased weekly in 10 mg increments to a maximum of 40 mg daily according to individual responses.

Children Aged Below 18 years

The efficacy has not been established.

Patients with Kidney/Liver Problem

If you have trouble with your liver or kidneys, your doctor may decide that you should have a lower dose of paroxetine than usual. If you have severe liver or kidney disease, the maximum dose is 20 mg per day.

-When to use it

Use as directed by your doctor or pharmacist. It is recommended that Paroxetine tablet should be swallowed rather than chewed.

- How long to use it

You are advised to take Paroxetine as long as your doctor tells you to.

- If you forget to use it

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

If you forget to take your dose, take it as soon as you remember. Skip the missed dose if it is almost time for your next dose. Do not take double dose to make up for a forgotten 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.

Taking too many tablets may cause drowsiness, nausea, vomiting, dilated pupils, dry mouth, fever, blood pressure changes, headache, involuntary muscle contractions, tremor, sweating, agitation, anxiety, irritability and increased heartbeat.

While you are using Paroxetine

- Things you must do

Tell your doctor:

- If you experience allergic reactions/ any of the unwanted side effects while taking the medicine.
- If you become pregnant while taking this medication

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

Take your medicine exactly as your doctor has told you.

If you start thinking about killing yourself, tell your doctor about this side effect right away.

- Things you must not do

Do not:

- give Paroxetine to anyone else even if they have the same condition as you
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist
- take more than the recommended dose unless your pharmacist or doctor tells you to
- stop taking the medicine unless advised by your doctor. Your doctor may want you to gradually reduce the amount of Paroxetine you are taking before stopping completely. This should help reduce the chance of withdrawal effects (see Side effects).

- Things to be careful of

Be careful when driving or operating machinery because Paroxetine may cause drowsiness. Avoid taking alcohol or other medications that will suppress your brain activities.

Suicidality in Children and Adolescent
Paroxetine should normally not be used for children and adolescents under 18 years. Paroxetine increases the risk of suicidal ideation and behavior in children. Despite this, your doctor may prescribe paroxetine for patients under

18 when he/she decides that this is in their best interests.

If your doctor has prescribed paroxetine for a patient 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 paroxetine is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in your child's behavior.

Side effects

Like all medicines, Paroxetine can cause side effects, although not everybody gets them. These effects can be serious but most of the time, they are mild and temporary.

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine:

Very Common:

- nausea
- impaired sexual function

Common:

- drowsiness, dizziness, difficulty in getting to sleep, tremor
- feeling sick, dry mouth, constipation, decreased appetite, diarrhoea
- feeling sweaty or shaky
- weakness
- blurred vision

Uncommon:

- abnormal bleeding
- confusion
- fast heartbeat
- brief increases or decreases in blood pressure
- skin rashes

Rare:

- low levels of sodium in the blood, especially in older people
- mood of excitement, over-activity and uninhibited behaviour
- fits or convulsions
- abnormal liver function

Very rare:

- low blood platelet count
- allergic reactions
- serotonin syndrome (a potential life-threatening set of symptoms including agitation, confusion, excess perspiration or sweating, overactive reflexes [such as a muscle spasm when you are lightly touched], hallucinations [hearing voices or seeing things which are not there])
- raised pressure in the eye
- rash caused by light
- swelling of the limbs, face, lips, mouth or throat

Unwanted effects that may occur on stopping treatment (withdrawal effect). Symptoms may include:

Common

- dizziness, sensory disturbances, disturbed sleep, anxiety

Uncommon

- agitation, nausea, sweating

If you are worried about withdrawal effects when stopping paroxetine, you may talk to your doctor or pharmacists.

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Paroxetine

- Storage

Keep out of reach of children.

Store below 30°C. Protect from light and 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

Oblong, white to off white film-coated tablet, shallow convex, "HD" embossed on one face and break bar on the other face.

- Ingredients

- Active ingredients

Each Paroxetine Tablet contains Paroxetine (as hydrochloride hemihydrate) 20 mg

- Inactive ingredients

- Dicalcium Phosphate Dihydrate
- Hydroxypropyl Methylcellulose
- Sodium Starch Glycolate
- Magnesium Stearate
- Isopropyl Alcohol
- Propylene Glycol
- Titanium Dioxide
- Talc

- MAL Number(s)

MAL11060012A

Manufacturer

HOVID Bhd.

Lot 56442, 7 ½ Miles, Jalan Ipoh/ Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.

121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.

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