

# PROZETINE CAPSULE

Fluoxetine Hydrochloride (20 mg)

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## What Prozetine is used for

Used to treat depression and obsessive compulsive disorder (OCD) (Excessive thoughts that lead to repetitive behaviors).

## How Prozetine works

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

## Before you use Prozetine

### - When you must not use it

Do not take this medicine if:

- you are allergic to fluoxetine 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.

Concurrent use of fluoxetine with MAOIs may result in gastrointestinal symptoms, hyperpyretic episodes (extremely high fever), hypertensive crises (sudden, severe rises in blood pressure), serotonin syndrome (a potentially life-threatening set of symptoms including confusion,

restlessness, shivering, and fast heartbeat), or death.

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 diabetes
- you have problems with your heart, kidney or liver
- you suffer from epilepsy or have had a fit in the past
- you have a history of mania (feeling elated or over-excited, which causes unusual behaviour)

### - Taking other medicines

Prozetine 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 form including any that you buy or obtained without a prescription.

They include:

- SSRI, tricyclic antidepressants (TCAs), and other medicines for depression or OCD.
- MAOI (see subsection *When you must not use it*)
- medicines used to relieve anxiety
- medicines used to control fits
- medicines used to treat heart conditions

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

## How to use Prozetine

### - 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:*

One capsule daily.

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

Initial dose of one capsule daily, increased after several weeks if there is no response to up to three capsules daily.

### - When to use it

Use as directed by your doctor or pharmacist. Swallow the capsule whole by mouth.

### - How long to use it

You are advised to take Prozetine 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 capsules may cause drowsiness, nausea, vomiting, seizures, increased heartbeat, tremor, agitation, restlessness and excitation.

## While you are using Prozetine

### - Things you must do

Tell your doctor/pharmacist:

- 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 Prozetine.

Take your medicine exactly as your doctor has told you.

### - Things you must not do

Do not:

- give Prozetine 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 Prozetine you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms (such as nausea, dizziness and lethargy).

### - Things to be careful of

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

### *Suicidality in Children and Adolescent*

Prozetine should normally not be used for children and adolescents under 18 years. Prozetine increases the risk of suicidal ideation and behaviour in children. Despite this, your doctor may prescribe Prozetine for patients under 18 when he/she decides that this is in their best interests.

If your doctor has prescribed Prozetine 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 Prozetine is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in your child's behaviour.

### Side effects

Like all medicines, Prozetine 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:

- drowsiness and fatigue
- dizziness
- nausea, vomiting
- stomach upset, diarrhoea
- loss of appetite, weight loss, dry mouth
- trouble sleeping
- nervousness, anxiety
- excessive sweating
- lesions of skin and mucous membrane
- convulsions or fits
- abnormal liver function test

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](http://portal.bpfk.gov.my) (Consumers→Reporting)

### Storage and Disposal of Prozetine

#### - Storage

Keep out of reach of children.

Store below 25°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

Bluish green opaque and ivory opaque with "PZ20" printed on one end and "Hovid" on the other end of the capsule filled with white to slight yellowish granules.

#### - Ingredients

- Active ingredients

Each Prozetine Capsule contains Fluoxetine (as hydrochloride) 20mg

- Inactive ingredients

- Lactose Monohydrate
- Cornstarch
- Crospovidone
- Povidone
- Magnesium Stearate

#### - MAL Number(s)

MAL08111809A

### 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.

### Date of revision

10/07/2015

### Serial Number

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