

PROVATINE CAPSULE

Fluoxetine (20mg)

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What PROVATINE is used for

PROVATINE is normally used to treat depression and the anxiety associated with depression, in adults. It is also used to obsessive-compulsive disorder and pre-menstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome (PMS).

Your doctor may have prescribed PROVATINE for another reason. Ask your doctor if you have any questions about why PROVATINE has been prescribed for you.

PROVATINE is available only with a doctor's prescription.

The use of this medicine in children and adolescents under the age of 18 years is not recommended.

How PROVATINE works

PROVATINE contains fluoxetine hydrochloride. It belongs to a group of medicines known as selective

serotonin reuptake inhibitors (SSRIs).

PROVATINE affects chemicals in the brain that may become unbalanced and cause depression, panic, anxiety, or obsessive compulsive symptoms.

Before you use PROVATINE

- 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.

Do not take PROVATINE if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. MAOI includes isocarboxacid, linezolid, phenelzine, rasagiline, selegiline and tranylcypromine.

Do not take PROVATINE if you are taking another medicine that affects the level of a chemical in the brain called serotonin.

Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI or other medicine that affects serotonin in the brain.

Do not use 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 using this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have any allergies to any other medicines, foods or preservatives.

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding. Your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you have or have had any medical conditions, including:

- Kidney disease
- Liver disease
- Diabetes
- Seizure or epilepsy
- Bleeding disorder

If you have not told your doctor about any of the above, tell him/her before you start taking PROVATINE.

- Taking other medicines

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

Some medicines and PROVATINE may interfere with each other. These include:

- Monoamine oxidase inhibitors
- Other medicine for depression
- Antipsychotic medicines such as haloperidol or clozapine
- Medicines used to control fits such as phenytoin or carbamazepine
- Lithium

- Medicines used to prevent blood clots, such as warfarin
- Benzodiazepines, such as diazepam and alprazolam
- Serotonergic drugs such as tramadol (used to relieve pain) and sumatriptan (used to treat migraine)
- St John's Wort

These medicines may be affected by PROVATINE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

If you not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use PROVATINE

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

These directions may differ from the information contained in this leaflet.

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

- How much to use

Your doctor will tell you how much PROVATINE you need to take each day.

It is important that you take PROVATINE as directed by your doctor. Do not take more than the recommended dose.

Depression:

The usual recommended dose is one capsule a day.

Obsessive compulsive disorder

A dose range of one to three capsule/s a day.

Premenstrual dysphoric disorder

The recommended dose is one capsule taken continuously throughout the menstrual cycle.

Your doctor may increase or decrease your dose depending on your condition. For any condition, the daily dose should not exceed 80mg.

- When to use it

PROVATINE is usually taken in the morning as a single dose.

Doses above 20mg per day should be administered twice daily (morning and afternoon).

Take your medicine at about the same time each day. Taking it at the same time each day will help you remember when to take it.

- How long to use it

Continue taking PROVATINE for as long as your doctor recommends.

The length of treatment with PROVATINE will depend on how quickly your symptoms improve.

Most medicines of this type take time to work so don't be discouraged if you do not feel better right away.

If you do not start to feel better in about four weeks, check with your doctor.

- If you forget to use it

If it is almost time for 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 capsules as you would normally.

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

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

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much PROVATINE capsule.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

- Things you must do

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

If you become pregnant while you are taking PROVATINE tell your doctor immediately. Your doctor will discuss with you the risks and benefits involved.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking PROVATINE.

The symptoms of depression or other psychiatric conditions

may include thoughts of harming yourself or suicide.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Suddenly stopping PROVATINE may cause symptoms such as dizziness, anxiety, headache, feeling sick or tingling or numbness of the hands or feet. Your doctor may want you to gradually reduce the amount of PROVATINE you are taking before stopping completely.

Do not let yourself run out of PROVATINE over the weekend or on holidays.

Do not take PROVATINE to treat any other complaints unless your doctor tells you to.

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

- Things to be careful of

Be careful driving or operating machinery until you know how PROVATINE affects you. PROVATINE may cause drowsiness in some people.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

- Nausea, vomiting
- Upset stomach
- Diarrhoea
- Loss of appetite, weight loss
- Dry mouth
- Drowsiness, weakness

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

Storage and disposal of PROVATINE

- Storage

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

If you take the capsules out of the pack, they may not keep well.

Keep your medicine in a place where the temperature will stay below 25°C. Protect from light.

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 it 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

Product Description

- What it looks like

A green/cream, size '3' capsule with markings 'DUO 861'.

- Ingredients

Active ingredient:

- Fluoxetine hydrochloride

Inactive ingredients:

- Lactose
- Magnesium stearate

- MAL number

MAL06011876A

Manufacturer

DUOPHARMA (M) SDN. BHD. (42491-M)
Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

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