

## FLUOX

*Fluoxetine hydrochloride Capsules 20 mg*

*Fluoxetine hydrochloride Dispersible Tablets 20 mg*



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### What is in this leaflet

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This leaflet answers some common questions about FLUOX.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FLUOX against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### What FLUOX is used for

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Your FLUOX capsules or dispersible tablets contain fluoxetine hydrochloride. They belong to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs).

FLUOX is normally used to treat depression and the anxiety associated with depression. It is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in 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. FLUOX works by correcting this chemical imbalance and may help relieve the symptoms of depression.

FLUOX is also used to treat bulimia nervosa (eating disorder) and obsessive-compulsive disorder (OCD). FLUOX may also be used to treat pre-menstrual dysphoric disorder (PMDD), a severe form of premenstrual syndrome (PMS).

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

There is no evidence that FLUOX is addictive.

FLUOX 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.

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### Before you take FLUOX

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**When you must not take it:**

**Do not take FLUOX if:**

- **You are allergic to fluoxetine or any other ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.**
- **You are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. Ask your doctor or**

**pharmacist if you are unsure as to whether or not you are taking a MAOI.**

- **You are taking another medicine that affects the level of a chemical in the brain called serotonin.**

**Do not take 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 taking this medicine, talk to your doctor.**

***Before you start to take it:***

**Tell your doctor if:**

- You have had an allergic reaction to any medicine that you have taken previously to treat your current condition.
- You have kidney or liver disease, diabetes, glaucoma or have ever had fits.
- You have a bleeding disorder.
- You are having electrical shock treatment.
- You are pregnant, plan to become pregnant, or are breastfeeding.
- You have allergies to any other medicines, foods, preservatives or dyes.

**If you are pregnant or plan to become pregnant** you need to discuss with your doctor the risks and benefits of taking FLUOX during pregnancy. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this

medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like FLUOX may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

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

### ***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 FLUOX may interfere with each other. These include:

- **Monoamine oxidase inhibitors**
- **Other antidepressants**
- **St John's Wort**
- **Lithium**
- **Warfarin and other medicines that may increase risk of bleeding**
- **Central nervous system active medicines** including phenytoin, alprazolam and diazepam.
- **Oral antidiabetic medicines or insulin.**

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

Your doctor and pharmacist have more information on medicines to

be careful with or avoid while taking FLUOX.

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## **How to take FLUOX**

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

They may differ from the information contained in this leaflet.

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

### ***How much to take***

Your doctor will tell you how much FLUOX you need to take each day. It is important that you take FLUOX as directed by your doctor. Do not take more than the recommended dose.

The usual daily dose for adults is:

- 20mg to treat depression.
- 60mg to treat bulimia nervosa.
- 20mg to 60mg to treat obsessive-compulsive disorder.
- 20mg continuously throughout the menstrual cycle for premenstrual dysphoric disorder.

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

FLUOX should not be used in children and adolescents (under 18 years of age).

### ***How to take it***

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

The capsule(s) should be swallowed whole with a glass of water.

The tablet(s) can either be swallowed with a glass of water or dispersed in water. To disperse your FLUOX tablet, place the tablet(s) in approximately 100mL ( $\frac{1}{2}$  glass) of water, swirl until tablet disperses, then drink immediately.

FLUOX can be taken with or without food.

### ***How long to take it***

For depression, the treatment period will depend on how quickly your symptoms improve. You may not feel better immediately as most antidepressants take time to work. Do not stop taking FLUOX even if you begin to feel better, unless your doctor tells you to do so. Make sure you do not run out of capsules or dispersible tablets. If you do not feel better in about four weeks, see your doctor.

For PMDD, initial treatment is limited to six months, after which your condition should be reassessed with your doctor regarding the benefit of continued therapy.

**Continue taking your medicine for as long as your doctor tells you.**

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

**If you forget a dose, just take the next dose when it is due.**

**Do not take more than one dose at a time to make up for missed doses.** This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

You should only take the number of capsules or dispersible tablets that you have been told. If you have taken too much FLUOX, some of the symptoms which you may experience are feeling sick in the stomach, vomiting, fits or convulsions, changes in mood ranging from drowsy to excited.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the**

**Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any FLUOX by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.** Take the pack of FLUOX with you if you can.

Keep telephone numbers for these places handy.

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## While you are taking FLUOX

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

**Tell all doctors, dentists and pharmacists who are treating you that you are taking FLUOX.**

Tell your doctor or pharmacist that you are taking FLUOX before you start any new medicine.

Tell your doctor if you develop a skin rash or hives while taking FLUOX.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**If you are about to have any blood tests, tell your doctor that you are taking this medicine.** It may interfere with the results of some tests.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

**Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity, akathisia (restlessness or difficulty sitting still), hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.**

**Tell your doctor immediately if you have any distressing thoughts (thoughts of suicide or self-harm) or experiences during this initial period or at any other time.**

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

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

Do not stop taking FLUOX or lower the dose without first checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

After you have stopped taking FLUOX, you should wait for at least 5 weeks before taking medications with MAOI activity.

**FLUOX may cause drowsiness in some people.** Be careful when driving, operating machinery or performing jobs that need you to be alert until you are certain that FLUOX does not affect your performance.

Your doctor may suggest avoiding alcohol while you are being treated for depression.

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## Side effects

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**Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking FLUOX.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

- Stomach or bowel problems (e.g. nausea, vomiting, diarrhoea, indigestion)

- Drowsiness or weakness
- Shakiness
- Trouble sleeping
- Changes in your sex drive or impotence
- Loss of appetite or weight loss
- Nervousness and anxiety
- Increased perspiration or sweating
- Headache
- Dry mouth
- Dizziness
- Yawning
- Impaired concentration or thought processes
- Memory impairment
- Unusual dreams
- Abnormal vision
- Changes in taste
- Palpitations
- Changes in frequency of urination.

These are the more common side effects of FLUOX.

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

- Any signs of bleeding
- Uncontrollable twitching or jerking movements
- Seizures.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**Tell your doctor immediately if you notice any of the following:**

- A rash or hives while taking FLUOX.
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- A serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

**These side effects are rare but serious. You may need urgent medical attention.**

See your doctor if you experience any of the following when you stop FLUOX treatment:

- Dizziness

- Tingling or numbness of the hands or feet
- Headache
- Anxiety
- Nausea.

These symptoms are generally not serious and disappear within a few days.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect, please tell your doctor or pharmacist.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

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## After using FLUOX

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### **Storage**

Keep your FLUOX capsules and dispersible tablets in the blister pack until it is time to take them.

Keep your FLUOX capsules and dispersible tablets in a cool dry place where the temperature stays below 25°C.

Do not store FLUOX 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 tells you to stop taking FLUOX or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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## Product description

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Your medicine is in the form of:

- Capsules in blister packs each containing 84 or 90 capsules; or
- Dispersible tablets in blister packs each containing 30 tablets.

### **Ingredients**

Each capsule or dispersible tablet contains the active ingredient fluoxetine hydrochloride equivalent to 20mg fluoxetine.

The capsules also contain:

- Lactose
- Maize starch
- Colloidal anhydrous silica
- Purified talc
- Magnesium stearate.

The dispersible tablets also contain:

- Microcrystalline cellulose
- Colloidal anhydrous silica
- Maize starch
- Crospovidone
- Saccharin sodium
- Magnesium stearate
- Peppermint powder.

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## If you want to know more

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Should you have any questions regarding this product, please contact your pharmacist or doctor.

### **Who supplies this medicine**

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Eilerslie,  
Auckland.

Telephone: (09) 579 2792

### **Date of Information**

17 August 2011  
(Based on datasheet dated 5 August 2011)