

# APO-Fluoxetine capsules

*Fluoxetine (as fluoxetine hydrochloride)*

## Consumer Medicine Information

*For a copy of a large print leaflet, Ph: 1800 195 055*

### What is in this leaflet

This leaflet answers some common questions about fluoxetine. 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 using this medicine 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 your medicine. You may want to read it again.

### What this medicine is used for

The name of your medicine is APO-Fluoxetine. It contains the active ingredient fluoxetine (as fluoxetine hydrochloride).

Fluoxetine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

Serotonin is one of the chemicals in your brain which helps control your mood. Fluoxetine and other SSRIs are thought to help by increasing the amount of serotonin in your brain.

Fluoxetine is used to treat:

- depression

- obsessive compulsive disorder (OCD)
- premenstrual dysphoric disorder (PDD)

Depression is longer lasting and/or more severe than the 'low moods' everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance 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. Fluoxetine corrects this chemical imbalance and may help relieve the symptoms of depression.

Check with your doctor if you need more information about obsessive compulsive disorder (OCD).

The symptoms of OCD vary from patient to patient.

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure you know how it affects you beforehand, as it can make some people dizzy or drowsy, and affect judgement, thinking and motor skills.

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

Your doctor may have prescribed this medicine for another reason.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

### Before you take this medicine

*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- any medicine containing fluoxetine
- any of the 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

**Do not take this medicine if you are taking other medicines called Monoamine Oxidase Inhibitors (MAOIs).**

These may be used for the treatment of depression (phenelzine, tranylcypromine or moclobemide), Parkinson's disease (selegiline) or infections (linezolid).

**Do not take fluoxetine until 14 days after stopping any MAOI, and do not take MAOIs until at least 5 weeks after stopping fluoxetine.**

Taking fluoxetine with a MAOI may cause a serious reaction with signs

such as a sudden increase in body temperature, very high blood pressure, rigid muscles, nausea, vomiting and/or fits (convulsions).

**Do not take this medicine if you are taking pimozide (Orap), a medicine used to treat disturbances in the way people think, feel or act.**

Taking pimozide together with fluoxetine may alter the rhythm of your heart.

**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 allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you are pregnant, or plan to become pregnant.**

There have been reports that babies exposed to fluoxetine and other antidepressants during the third trimester of pregnancy may develop complications after birth.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

**Tell your doctor if you are breastfeeding, or plan to breastfeed.**

Fluoxetine can pass into breast milk. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- epilepsy, fits or convulsions (seizures)
- heart disease or a heart attack
- diabetes
- breast cancer
- liver disease
- kidney disease

- a bleeding disorder or a tendency to bleed more than usual
- thoughts or actions relating to self-harm or suicide
- bipolar disorder
- intolerance or allergy to lactose - these capsules contain lactose

**Tell your doctor if you drink alcohol.**

Although drinking alcohol is unlikely to affect your response to fluoxetine, your doctor may suggest avoiding alcohol while you are being treated for depression.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

*Taking other medicines*

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

Some combinations of medicines may increase the risk of having serious side effects. These serious side effects may be life-threatening.

**In particular, do not take fluoxetine if you are taking the following other medicines:**

- pimozide, used to treat disorders which affect the way you think, feel or act
- monoamine oxidase inhibitors (MAOIs), which are also used for treating depression (phenelzine, tranylcypromine or moclobemide), certain infections (linezolid), and Parkinson's disease (selegiline)

Some other medicines may interact with fluoxetine. These include:

- other medicines used to treat depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD), such as sertraline, citalopram, paroxetine and fluvoxamine
- medicines used to treat anxiety called benzodiazepines (e.g. diazepam, alprazolam)

- medicines called antipsychotics, used to treat certain mental and emotional conditions (e.g. haloperidol and clozapine)
- lithium, used to treat mood swings and some types of depression
- medicines used to control fits, such as carbamazepine and phenytoin
- warfarin, used to thin the blood
- sleeping tablets or sedatives
- flecainide, used to treat irregular heart beats
- tryptophan, contained in some multivitamin and herbal preparations
- sumatriptan, and other medicines called triptans used to treat migraines
- tramadol, a strong pain-killer
- St John's wort (*Hypericum perforatum*), a herbal remedy
- tamoxifen, a medicine for treatment or prevention of breast cancer.

These medicines may be affected by fluoxetine 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 this medicine.**

**Do not start taking other medicines for depression without talking to your doctor first. Do this even if you have already stopped taking fluoxetine.**

Monoamine oxidase inhibitors (MAOIs), which are other medicines used for depression, may interfere with fluoxetine. You should not start a MAOI for at least 5 weeks after stopping fluoxetine.

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## How to take this medicine

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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 directions, ask your doctor or pharmacist for help.**

### *How much to take*

**The usual starting dose of fluoxetine is one 20 mg capsule each morning.**

Your doctor may increase or decrease this dose depending on how you respond to this medicine.

For premenstrual dysphoric disorder (PMDD), fluoxetine may be prescribed to be taken every day or only during a certain part of the month. Your doctor will prescribe the dosing schedule that is right for you

**Do not stop taking your medicine or change your dosage without first checking with your doctor.**

### *How to take it*

**Swallow the capsule whole with a full glass of water.**

### *When to take it*

**Fluoxetine is usually taken as a single dose in the morning.**

If your doctor tells you to take fluoxetine twice a day, take one dose in the morning and one at midday.

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

### *How long to take it for*

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

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to

work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 to 6 weeks to feel any real improvement.

Even when you feel well, you will usually have to take this medicine for several months or even longer to make sure that the benefits will last.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

**You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.**

Contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

### *If you forget to take it*

**If it is almost time to take 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 medicine as you would normally.**

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

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.**

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

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

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or**

**go to Accident and Emergency at the nearest hospital, if you think that 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 fluoxetine you may be sick or feel sick, agitated, restless, excitable or hyperactive or you may have convulsions (fits).

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## While you are taking this medicine

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### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking fluoxetine.**

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

**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 become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

Symptoms such as feeding difficulty, vomiting, tremor, irritability and constant crying have been reported in newborn babies after mothers have taken fluoxetine in the last 3 months of pregnancy.

**Tell your doctor if you develop a rash or hives.**

**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.

**Tell your doctor if you have not taken your medicine exactly as prescribed.**

Otherwise the doctor will think that it is not working and change your treatment unnecessarily

**Tell your doctor if you feel that the medicine is not helping your condition.**

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse during the first one to two months of taking fluoxetine until the medicine starts to work completely. This is more likely to occur in young adults under 25 years of age (i.e. 18 to 24 years of age) and have not used antidepressant medicines before.

**If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking fluoxetine, contact a doctor immediately, or even go to the nearest hospital for treatment:**

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation or any other unusual changes in behaviour or mood
- worsening of depression.

**All mentions of suicide or violence must be taken seriously.**

**Tell your doctor if you get a headache or start to feel dizzy, confused, forgetful, weak, unsteady or unable to concentrate.**

Some people (especially older people and/or those taking diuretics/water tablets) may experience a lack of sodium in the blood when taking this medicine. Make sure to drink plenty of fluids.

**If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness,**

**thoughts of suicide, bursts of unusual energy, anger or aggression, or if you become particularly agitated or restless.**

This will help your doctor to determine the best treatment for you.

### *Things you must not do*

**Do not take this medicine 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.**

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

If you stop taking it suddenly, your condition may worsen, or you may have unwanted side effects.

Suddenly stopping fluoxetine 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 fluoxetine you are taking before stopping completely.

**Do not take the herbal remedy St. John's Wort while you are being treated with fluoxetine.**

If you are already taking the herbal remedy, stop taking St. John's Wort and mention it to your doctor at your next visit.

### *Things to be careful of*

**Be careful when driving or operating machinery until you know how this medicine affects you.**

This medicine may make some people dizzy or drowsy, and affect judgement, thinking and motor skills in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness or drowsiness may be worse. Your doctor may suggest avoiding alcohol while you are being treated for depression.

**If you are diabetic, be sure to regularly monitor your blood glucose levels and tell your doctor if these change significantly.**

**You should wait at least 5 weeks after stopping fluoxetine before starting any medicines called MAOIs.**

You should be aware that people who take antidepressants have an increased risk of having a bone fracture, especially when first taking fluoxetine.

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## Side effects

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

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

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

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

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

- difficulty sleeping, unusual dreams, yawning
- excessive sweating, chills, flushing
- indigestion, nausea, vomiting
- diarrhoea
- loss of appetite, weight loss, changes in taste, dry mouth, problems swallowing, heartburn or chest pain, often after swallowing food or drink
- changes in vision
- unusual taste
- twitching, trembling
- drowsiness, tiredness, weakness, fatigue
- headache
- confusion
- impaired memory
- dizziness (sometimes when you stand up too quickly)

- low blood pressure
- impaired sexual function
- passing urine more frequently than normal
- unusual hair loss or thinning
- mild rash, itching or hives
- increased sensitivity of the skin to sun
- grinding your teeth
- painful or enlarged breasts
- unusual vaginal bleeding
- nosebleed
- lesions of skin and mucous membranes
- fever and joint aches
- changes in vision

The above list includes the more common side effects of your medicine.

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

- abnormal bleeding or bruising
- abnormal or suspicious thinking
- feeling abnormal
- feeling unbalanced on your feet
- problems moving smoothly, or making unusual movements
- agitation, nervousness, anxiety, worsening of depression
- restlessness and/or a need to move often (akathisia).
- fixed, staring eyes
- general swelling or swollen hands, ankles, feet or face or eye area due to fluid build-up

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

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- sudden switch of mood to one of excitement, overactivity, talkativeness, uninhibited behaviour or aggression, or if you become particularly agitated or restless.
- changing emotions, including crying, changes in mood, trying

to harm yourself, thoughts of suicide and attempting suicide

- problems with breathing
- jaundice (yellowing of the skin and/or eyes), with or without other signs of hepatitis or liver problems (loss of appetite, tiredness, feeling or being sick, dark urine, stomach pain or swelling, confusion, unconsciousness)
- convulsions, fits
- palpitations, fast or irregular heart beats
- difficulty in urinating
- sudden fever
- hallucinations, loss of coordination or confusion
- overactive reflexes
- a collection of symptoms including weight gain (despite loss of appetite), feeling and being sick, muscle weakness and irritability
- skin rash combined with inflamed blood vessels
- Serotonin syndrome - sudden fever, hallucinations, restlessness, loss of coordination, confusion and overactive reflexes with sweating, fast heart beat and muscle stiffness, nausea vomiting and fits, which may lead to loss of consciousness
- unusual muscle stiffness (with or without raised body temperature), poor control of movement, muscle spasms, tremors or twitches
- uncontrollable twitching or jerking movements of the arms and legs
- thoughts of suicide or attempting suicide or self-harm
- severe rash, with blisters and/ or excessive peeling of skin
- you notice your stool is red, dark brown or black
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts

of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may occur in some patients.

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## Storage and disposal

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### Storage

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

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 30°C.**

**Protect it from sunlight. 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 this medicine 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 this medicine 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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### *What APO-Fluoxetine looks like*

Green/off-white hard gelatin, self-locked, size 2 capsule imprinted with 'FLX' and 'MIL' on cap/body in black

edible ink, containing white powder.

AUST R 273924.

Blister pack of 28 capsules.

### *Ingredients*

Each capsule contains 20 mg of fluoxetine (as fluoxetine hydrochloride) as the active ingredient.

It also contains the following inactive ingredients:

- pre-gelatinised maize starch
- gelatin\*
- brilliant blue FCF
- iron oxide yellow
- titanium dioxide
- sodium lauryl sulfate
- black edible ink (contains shellac, ethanol absolute, isopropyl alcohol, butan-1-ol, propylene glycol, iron oxide black and purified water)

\*May contain trace amounts of phenylalanine and sulfites.

This medicine is lactose-free, gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

### *Sponsor*

Arrotex Pharmaceuticals Pty Ltd  
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