

APO-Fluoxetine Capsules

Contains the active ingredient fluoxetine (as fluoxetine hydrochloride)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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).

It is used to treat:

- depression
- obsessive compulsive disorder (OCD).

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.

This medicine is available only with a doctor's prescription.

How it works

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.

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.

Use in children

Fluoxetine is not recommended for use in children and adolescents under 18 years of age.

Before you take this medicine

When you must not take it

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, 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).
- You are taking pimozide (Orap), a medicine used to treat disturbances in the way people think, feel or act.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to fluoxetine or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include 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; fainting or hayfever-like symptoms
If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. 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.
3. You are currently pregnant or you 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.
 4. You are currently breast-feeding or you plan to breast-feed. 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.
 5. You are receiving electroconvulsive therapy (ECT)
 6. You are planning to have surgery or an anaesthetic.
 7. You are currently receiving or are planning to receive dental treatment.
 8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

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, moclobemide), certain infections (linezolid), and Parkinson's disease (selegiline).

(see also "When you must not take it", starting earlier in this leaflet).

Some other medicines may interact with fluoxetine. These include:

- other medicines used to treat depression or obsessive compulsive disorder, 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, a medicine used to treat mood swings and some types of depression
- medicines used to control fits, such as carbamazepine and phenytoin
- warfarin, a medicine used to thin the blood
- sleeping tablets or sedatives
- flecainide, a medicine 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with fluoxetine.

Tell your doctor also if you are planning to drink alcohol whilst taking this medicine.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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.

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 should only be taken by adults over 18 years of age.

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

It does not matter if you take it before, with 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.

Make sure you have enough to last over weekends and holidays.

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.

Also 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 missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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).

While you are taking this medicine

Things you must do

People taking fluoxetine may be more likely to think about killing themselves or actually try to do so, especially when fluoxetine is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using fluoxetine who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

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 if you are a young adult, i.e. 18 to 24 years of age, and you 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
- worsening of depression.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant. 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.
- you are breast-feeding or are planning to breast-feed

- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital
- you develop a rash or hives
- you have not taken your medicine exactly as prescribed. Otherwise the doctor will think that it is not working and change your treatment unnecessarily
- you feel that the medicine is not helping your condition.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first 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.

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.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking fluoxetine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

This list includes the more common side effects. Mostly, these are mild:

- 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.

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- 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
- a collection of symptoms including weight gain (despite loss of appetite), feeling and being sick, muscle weakness and irritability
- uncontrollable twitching or jerking
- 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
- uncontrollable twitching or jerking movements of the arms and legs
- allergic reaction, such as rash, itching or hives on the skin; swelling of the face, lips, tongue, mouth, throat or other parts of the body; shortness of breath, wheezing or difficulty swallowing or breathing
- 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.

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

Allergic reactions

If you think you are having an allergic reaction to fluoxetine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

Storage and disposal

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 25°C.

Protect it from moisture. 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Fluoxetine looks like

APO-Fluoxetine 20 mg capsules:

Capsule cap is an opaque light green and capsule body is ivory. 'APO' and '20' are printed in black ink on the opposing capsule body and cap.

Blister packs 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:

- anhydrous lactose
- maize starch
- stearic acid
- purified talc
- gelatin
- brilliant blue FCF
- quinoline yellow
- sunset yellow FCF
- titanium dioxide
- sodium lauryl sulfate
- sorbitan monolaurate
- TekPrint SW-9008 black ink
- TekPrint SW-9009 black ink

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

Australian Registration Numbers

APO-Fluoxetine 20 mg Capsules:

Blister packs
AUST R 160765.

Sponsor

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