

APO-FLUOXETINE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking APO-FLUOXETINE?

APO-FLUOXETINE contains the active ingredient fluoxetine hydrochloride. APO-FLUOXETINE is used to treat depression, obsessive compulsive disorder (OCD) and premenstrual dysphoric disorder (PMDD).

For more information, see Section [1. Why am I taking APO-FLUOXETINE?](#) in the full CMI.

2. What should I know before I take APO-FLUOXETINE?

Do not use if you have ever had an allergic reaction to APO-FLUOXETINE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take APO-FLUOXETINE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-FLUOXETINE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take APO-FLUOXETINE?

- Your doctor will tell you how much APO-FLUOXETINE you need to take each day.

More instructions can be found in Section [4. How do I take APO-FLUOXETINE?](#) in the full CMI.

5. What should I know while taking APO-FLUOXETINE?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are taking APO-FLUOXETINE.Tell your doctor immediately if you become pregnant while taking APO-FLUOXETINE.Tell your doctor immediately if you have thoughts about harming or killing yourself.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine or lower the dosage without checking with your doctor.Do not take the herbal remedy St. John's Wort while you are being treated with APO-FLUOXETINE.Do not give APO-FLUOXETINE to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">Do not drive or operate machinery until you know how APO-FLUOXETINE affects you.APO-FLUOXETINE may cause impaired judgement, reduce coordination, or drowsiness in some people.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">Keep your capsules in the blister pack until it is time to take them.Keep your capsules in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking APO-FLUOXETINE?](#) in the full CMI.

6. Are there any side effects?

Common side effects include fatigue, weakness, diarrhoea, chills, headache, nausea, vomiting, weight loss, dry mouth, trouble sleeping, anxiety, abnormal thoughts/dreams, drowsiness, dizziness, sweating, twitches, rash, itch, sexual disturbances, frequent urination, changes in taste and changes in vision. Serious side effects may include serious allergic reactions, muscle spasms, tremors, seizures, fast, irregular heartbeat, ECG changes, abnormal bleeding/bruising, sudden mood swings, confusion, loss of coordination, Stevens-Johnson syndrome, erythema multiforme and serotonin syndrome.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-FLUOXETINE

Active ingredient: *fluoxetine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO-FLUOXETINE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO-FLUOXETINE.**

Where to find information in this leaflet:

- [1. Why am I taking APO-FLUOXETINE?](#)
- [2. What should I know before I take APO-FLUOXETINE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APO-FLUOXETINE?](#)
- [5. What should I know while taking APO-FLUOXETINE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking APO-FLUOXETINE?

APO-FLUOXETINE contains the active ingredient fluoxetine hydrochloride. APO-FLUOXETINE belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

APO-FLUOXETINE is used to treat:

- depression
- obsessive compulsive disorder (OCD)
- premenstrual dysphoric disorder (PMDD).

2. What should I know before I take APO-FLUOXETINE?

Warnings

Do not take APO-FLUOXETINE if:

- you are allergic to fluoxetine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days.
- you are taking another medicine called pimozide to treat disturbances in thinking, feelings and behavior.

Check with your doctor if you:

- have any other medical conditions, such as:
 - liver problems
 - heart conditions
 - raised eye pressure

- kidney problems
- seizures or fits
- diabetes
- bleeding disorders
- any other medical condition.
- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition.
- drink alcohol.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking APO-FLUOXETINE during pregnancy. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like APO-FLUOXETINE may affect your newborn baby and they may experience irritability, constant crying, feeding difficulties, vomiting, fluctuating temperature, seizures or fits, tremors, jitteriness, bluish appearance (cyanosis), breathing interruptions, low blood sugar, muscle stiffness, muscle weakness, or over responsive reflexes. These symptoms are uncommon and may be due to the effect of APO-FLUOXETINE or the discontinuation of APO-FLUOXETINE.

When used during pregnancy, particularly in late pregnancy, medicines like APO-FLUOXETINE may increase the risk of a serious condition in babies called persistent pulmonary hypertension (PPHN) which may cause the baby to breathe faster and appear bluish. If this happens to your baby, you should contact your doctor and/or go straight to the Emergency Department at your nearest hospital.

If you take APO-FLUOXETINE near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth. Tell your doctor or midwife if you are taking APO-FLUOXETINE so that they can advise you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding while on APO-FLUOXETINE is not recommended.

Use in children

APO-FLUOXETINE is not recommended for use by children under the age of 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Some medicines may be affected by APO-FLUOXETINE or may affect how it works. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression.

You should stop taking MAOIs at least two weeks before starting APO-FLUOXETINE. If you do take APO-FLUOXETINE while you are taking a MAOI, you may experience elevated body temperature, muscle stiffness, involuntary muscle jerking, fluctuations of vital signs (blood pressure, heart rate, breathing rate) and mental state from extreme agitation progressing to confusion and coma (a condition called serotonin syndrome).

- tamoxifen, a medicine used to treat breast cancer.
- lithium, a medicine used to treat mood swings and some types of depression.
- serotonin and noradrenaline reuptake inhibitors (SNRIs), SSRIs, tricyclic antidepressants and other medicines for depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD).
- sleeping tablets or sedatives.
- medicines used to relieve anxiety.
- medicines used to treat certain mental and emotional conditions, also called antipsychotics.
- medicine used to treat disturbances in thoughts, feelings and behaviour, such as pimozide.
- medicines used to control seizures, such as phenytoin and carbamazepine.
- medicines used to prevent blood clots, such as warfarin.
- flecainide, a medicine used to treat some heart conditions.
- tryptophan.
- St John's Wort.
- medicines used to relieve pain, such as tramadol.
- triptan medicines used to treat migraine, such as sumatriptan.

Do not start taking other medicines for depression without checking with your doctor. Do this even if you have already stopped taking APO-FLUOXETINE.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-FLUOXETINE.

4. How do I take APO-FLUOXETINE?

How much to take

- The usual dose for APO-FLUOXETINE is one capsule taken once a day. Your doctor may increase or decrease your dose depending on your condition.
- For premenstrual dysphoric disorder (PMDD), APO-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.

- Follow the instructions provided and use APO-FLUOXETINE until your doctor tells you to stop.

When to take APO-FLUOXETINE

- APO-FLUOXETINE should be taken as a single morning dose.

If your doctor tells you to take APO-FLUOXETINE twice a day, take a dose in the morning and at noon. Take your medicine at about the same time each day.

How to take APO-FLUOXETINE

- Swallow the capsules whole with a glass of water.
- It does not matter if you take this medicine before or after food.

How long to take APO-FLUOXETINE

- Continue to take APO-FLUOXETINE for as long as your doctor recommends.
- The length of treatment with APO-FLUOXETINE will depend on how quickly your symptoms improve.
- Most medicines of this type take time to work so do not be discouraged if you do not feel better right away. While some symptoms will be relieved sooner than others, APO-FLUOXETINE commonly takes two to four weeks before improvement is really apparent.
- If you do not start to feel better in about four weeks, check with your doctor.

If you forget to take APO-FLUOXETINE

APO-FLUOXETINE should be taken regularly at the same time each day.

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 medicine as you would normally.

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

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

If you take too much APO-FLUOXETINE

If you think that you have taken too much APO-FLUOXETINE, you may need urgent medical attention. Symptoms of an overdose may include nausea (feeling sick), vomiting, seizures or fits, fast or slow heartbeat or change in heart rhythm, breathing difficulty, altered level of alertness from excitation to coma.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking APO-FLUOXETINE?

Things you should do

Tell your doctor if you become pregnant or start breastfeeding while taking APO-FLUOXETINE. Your doctor will discuss the risks and benefits of taking APO-FLUOXETINE during pregnancy or breastfeeding.

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

The symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or suicide. These symptoms may continue or get worse during the first one or two months of treatment until the full antidepressant effect of APO-FLUOXETINE becomes apparent. This is more likely to occur in young adults under 25 years of age.

If you or someone you know is demonstrating any of the following warning signs, call your doctor straight away or go to the Emergency Department at your nearest hospital:

- Worsening of your depression.
- Thoughts or talk of death or suicide.
- Thoughts or talk of self-harm or harm to others.
- Any recent attempts at self-harm.
- Increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Remind any doctor, dentist or pharmacist you visit that you are taking APO-FLUOXETINE. If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking APO-FLUOXETINE.

Things you should not do

- Do not stop taking this medicine or lower the dosage without checking with your doctor. Suddenly stopping APO-FLUOXETINE may cause symptoms such as dizziness, sleep disturbance, headache, irritability, anxiety, agitation, nausea, confusion, weakness, and tingling or numbness in the hands or feet. Your doctor may want you to gradually reduce the amount of APO-FLUOXETINE you are taking before stopping completely.
- Do not take the herbal remedy St. John's Wort while you are being treated with APO-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.
- Do not give APO-FLUOXETINE to anyone else, even if they have the same condition as you.
- Do not let yourself run out of APO-FLUOXETINE over the weekend or on holidays.
- Do not take APO-FLUOXETINE to treat any other complaints unless your doctor tells you to.

- Do not take APO-FLUOXETINE if the packaging is torn or shows signs of tampering or the capsules do not look quite right.

Driving or using machines

Do not drive or use any machines or tools until you know how APO-FLUOXETINE affects you.

APO-FLUOXETINE may cause impaired judgement, reduced coordination, or drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep your capsules in a cool dry place where the temperature stays below 25°C.
- Keep your capsules in the blister pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: <ul style="list-style-type: none">• Nausea, vomiting.• Upset stomach, diarrhoea.• Loss of appetite, weight loss, changes in taste, dry mouth. Nervous system: <ul style="list-style-type: none">• Drowsiness.• Flushing.• Nervousness, anxiety.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Dizziness. • Abnormal thoughts. • Headache. <p>Sleep related:</p> <ul style="list-style-type: none"> • Trouble sleeping, unusual dreams. <p>Skin related:</p> <ul style="list-style-type: none"> • Itch. • Rash. • Sweating. <p>Eye related:</p> <ul style="list-style-type: none"> • Changes in vision. <p>Muscle related:</p> <ul style="list-style-type: none"> • Twitches. <p>General symptoms:</p> <ul style="list-style-type: none"> • Fatigue, weakness. • Yawning. • Allergic reactions. • Chills. • Sexual disturbances (decreased sexual drive, problems with orgasm, ejaculation or erection). In some cases, these symptoms have continued after stopping treatment. • More frequent urination. 	

Serious side effects

Serious side effects	What to do
<p>Serious allergic reaction:</p> <ul style="list-style-type: none"> • 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, or rash, itching or hives on the skin. <p>Nervous system:</p> <ul style="list-style-type: none"> • Muscle spasms. • Tremors. • Seizures or fits. • Loss of coordination. • Confusion. • Feeling confused, feeling restless, agitation, mood swings, sweating, shaking, diarrhoea, shivering, tremor, loss of coordination, overactive reflexes, hallucinations, sudden jerks in your muscles or a fast heart beat (these may be symptoms of a rare condition called serotonin syndrome). • Sudden switches of mood to one of overactivity and uninhibited behaviour. <p>Heart related:</p> <ul style="list-style-type: none"> • Fast, irregular heartbeat. • ECG changes. <p>General symptoms:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Abnormal bleeding, or bruising. • A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome). • Severe skin rash, which may blister and looks like small targets (central dark spots surround by a paler area, with a dark ring around the edge) (erythema multiforme). 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-FLUOXETINE contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • Fluoxetine hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Pregelatinised maize starch • Gelatin • Brilliant blue FCF • Iron oxide yellow • Titanium dioxide • Sodium lauryl sulfate • Black edible ink <p>In addition, the black printing ink contains the following ingredients:</p> <ul style="list-style-type: none"> • Shellac • Ethanol absolute • Isopropyl alcohol • Butan-1-ol • Propylene glycol • Iron oxide black • Purified water

Potential allergens	May contain trace amounts of phenylalanine and sulfites.
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This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What APO-FLUOXETINE looks like

APO-FLUOXETINE capsules are green/off-white hard gelatin self locked capsules of size '2' imprinted with 'FLX' and 'MIL' on cap/body in black edible ink containing white powder.

APO-FLUOXETINE 20 mg capsules are available in packs of 28. (AUST R 273924).

Who distributes APO-FLUOXETINE

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in March 2024