

# Fluoxetine Sandoz®

## 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 using Fluoxetine Sandoz?

Fluoxetine Sandoz contains the active ingredient fluoxetine hydrochloride. Fluoxetine Sandoz is used to treat depression and obsessive compulsive disorder (OCD).

For more information, see Section [1. Why am I using Fluoxetine Sandoz?](#) in the full CMI.

### 2. What should I know before I use Fluoxetine Sandoz?

Do not use if you have ever had an allergic reaction to Fluoxetine Sandoz 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 use Fluoxetine Sandoz?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Fluoxetine Sandoz 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 use Fluoxetine Sandoz?

- Your doctor will tell you how much Fluoxetine Sandoz you need to take each day.

More instructions can be found in Section [4. How do I use Fluoxetine Sandoz?](#) in the full CMI.

### 5. What should I know while using Fluoxetine Sandoz?

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

For more information, see Section [5. What should I know while using Fluoxetine Sandoz?](#) 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.

# Fluoxetine Sandoz®

Active ingredient(s): *fluoxetine (as hydrochloride)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Fluoxetine Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fluoxetine Sandoz.**

Where to find information in this leaflet:

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

### 1. Why am I using Fluoxetine Sandoz?

**Fluoxetine Sandoz contains the active ingredient fluoxetine hydrochloride.** Fluoxetine Sandoz 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.

**Fluoxetine Sandoz is used to treat:**

- depression
- obsessive compulsive disorder (OCD).

### 2. What should I know before I use Fluoxetine Sandoz?

#### Warnings

**Do not use Fluoxetine Sandoz 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 use 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 pimozone to treat disturbances in thinking, feelings and behavior.
- you are taking another medicine called metoprolol to treat cardiac failure.

**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 mental 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 Fluoxetine Sandoz during pregnancy. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Fluoxetine Sandoz 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 Fluoxetine Sandoz or the discontinuation of Fluoxetine Sandoz.

When used during pregnancy, particularly in late pregnancy, medicines like Fluoxetine Sandoz 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 Fluoxetine Sandoz 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 Fluoxetine Sandoz so that they can advise you.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Breastfeeding while on Fluoxetine Sandoz is not recommended.

### Use in children and adolescents

Fluoxetine Sandoz is not recommended for use by children and adolescents 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 Fluoxetine Sandoz or may affect how well 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 Fluoxetine Sandoz. If you do take Fluoxetine Sandoz 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
- metoprolol, a medicine used to treat cardiac failure.

**Do not start taking other medicines for depression without checking with your doctor. Do this even if you have already stopped taking Fluoxetine Sandoz.**

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fluoxetine Sandoz.**

## 4. How do I use Fluoxetine Sandoz?

### How much to take

- The usual dose is one capsule taken once a day. Your doctor may increase or decrease your dose depending on your condition.
- Follow the instructions provided and use Fluoxetine Sandoz until your doctor tells you to stop.

### When to take Fluoxetine Sandoz

- Fluoxetine Sandoz is usually taken as a single morning dose.  
If your doctor tells you to take it 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 Fluoxetine Sandoz

- 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 Fluoxetine Sandoz

- Continue to take Fluoxetine Sandoz for as long as your doctor recommends.
- The length of treatment with Fluoxetine Sandoz 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. While some symptoms will be relieved sooner than others, Fluoxetine Sandoz 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 Fluoxetine Sandoz

Fluoxetine Sandoz should be used regularly at the same time each day.

If you miss your dose at the usual time, take your dose as soon as you remember, and continue to take it as you would normally.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**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 Fluoxetine Sandoz

If you think that you have used too much Fluoxetine Sandoz, 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 using Fluoxetine Sandoz?

### Things you should do

**Tell your doctor if you become pregnant or start breastfeeding while taking Fluoxetine Sandoz.** Your doctor will discuss the risks and benefits of taking Fluoxetine Sandoz 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 Fluoxetine Sandoz 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 Fluoxetine Sandoz. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Fluoxetine Sandoz.

### Things you should not do

- Do not stop taking this medicine or lower the dosage without checking with your doctor. Suddenly stopping Fluoxetine Sandoz 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 Fluoxetine Sandoz you are taking before stopping completely.
- Do not take the herbal remedy St. John's Wort while you are being treated with Fluoxetine Sandoz. 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 Fluoxetine Sandoz to anyone else, even if they have the same condition as you.
- Do not let yourself run out of Fluoxetine Sandoz over the weekend or on holidays.
- Do not take Fluoxetine Sandoz to treat any other complaints unless your doctor tells you to.
- Do not take Fluoxetine Sandoz 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 Fluoxetine Sandoz affects you.**

Fluoxetine Sandoz 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 Fluoxetine Sandoz, 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
<p><b>Gastrointestinal:</b></p> <ul style="list-style-type: none"><li>• nausea, vomiting</li><li>• upset stomach, diarrhoea</li><li>• loss of appetite, weight loss, changes in taste, dry mouth</li></ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"><li>• drowsiness</li><li>• flushing</li><li>• nervousness, anxiety</li><li>• dizziness</li><li>• abnormal thoughts</li><li>• headache</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p><b>Sleep related:</b></p> <ul style="list-style-type: none"> <li>trouble sleeping, unusual dreams</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>itch</li> <li>rash</li> <li>sweating</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>changes in vision</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>twitches</li> </ul> <p><b>General symptoms:</b></p> <ul style="list-style-type: none"> <li>fatigue, weakness</li> <li>yawning</li> <li>allergic reactions</li> <li>chills</li> <li>sexual disturbances (decreased sexual drive, problems with orgasm, ejaculation or erection). In some cases, these symptoms have continued after stopping treatment</li> <li>more frequent urination</li> </ul>	
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<p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>fast, irregular heartbeat</li> <li>ECG changes</li> </ul> <p><b>General symptoms:</b></p> <ul style="list-style-type: none"> <li>abnormal bleeding or bruising</li> <li>a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)</li> <li>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)</li> </ul>	
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**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](http://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.**

### Serious side effects

Serious side effects	What to do
<p><b>Serious allergic reaction:</b></p> <ul style="list-style-type: none"> <li>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</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>muscle spasms</li> <li>tremors</li> <li>seizures or fits</li> <li>loss of coordination</li> <li>confusion</li> <li>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)</li> <li>sudden switches of mood to one of overactivity and uninhibited behaviour</li> </ul>	<p><b>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.</b></p>

## 7. Product details

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

### What Fluoxetine Sandoz contains

<b>Active ingredient (main ingredient)</b>	fluoxetine hydrochloride
<b>Other ingredients (inactive ingredients)</b>	pregelatinised maize starch dimeticone 350 gelatin titanium dioxide iron oxide yellow CI 77492 patent blue V CI42051
<b>Potential allergens</b>	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 Fluoxetine Sandoz looks like**

Fluoxetine Sandoz comes in capsules.

Fluoxetine Sandoz 20mg - green capsule.

Available in blister packs of 28 capsules. (AUST R 64564)

## **Who distributes Fluoxetine Sandoz**

Sandoz Pty Ltd

100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

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