

Fluoxetine Sandoz®

fluoxetine (as hydrochloride) capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fluoxetine Sandoz.

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 this medicine against the benefits it is expected to 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.

What Fluoxetine Sandoz is used for

This medicine is used to treat:

- depression
- obsessive compulsive disorder (OCD).

It contains the active ingredient fluoxetine hydrochloride.

Fluoxetine hydrochloride belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). It works by inhibiting the neuronal uptake of serotonin in the central nervous system. Serotonin is one of several brain chemicals called amines which are involved in controlling mood.

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.

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

Before you take Fluoxetine Sandoz

When you must not take it

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

- fluoxetine hydrochloride, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

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 another medicine for depression called monoamine oxidase inhibitor (MAOI), or have been taking a MAOI within the last 14 days.**

Examples of MAOIs are phenelzine and tranylcypromine. There may be others so please check with your doctor. If you do take Fluoxetine Sandoz while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

- **you are taking pimozone, a medicine to treat disturbances in thinking, feelings and behaviour.**

Taking pimozone together with

Fluoxetine Sandoz may alter the rhythm of your heart.

- **you are taking metoprolol, a medicine to treat cardiac failure**

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering or the capsules do not look quite right.

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.

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy. If Fluoxetine Sandoz is taken during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed while you are using Fluoxetine Sandoz.

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.

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

- kidney problems
- liver problems
- diabetes
- fits
- a bleeding disorder or a tendency to bleed more than usual.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get 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 and Fluoxetine Sandoz may interfere with each other. 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
- lithium, a medicine used to treat mood swings and some types of depression
- SNRIs, SSRIs and other medicines for depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD)

- metoprolol, used to treat cardiac failure
- mequitazine, used to treat allergies and rhinitis
- sleeping tablets or sedatives
- medicines used to relieve anxiety
- medicines used to treat certain mental and emotional conditions, also called antipsychotics
- medicines used to treat disturbances in thinking, feelings and behaviour, such as pimozone
- medicines used to control fits
- 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
- sumatriptan, a medicine used to treat migraine
- tamoxifen, a medicine used to treat or prevent breast cancer.

These medicines may be affected by Fluoxetine Sandoz 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 can tell you what to do if you are taking any other medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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 checking with your doctor. Do this even if you have already stopped taking Fluoxetine Sandoz.

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

How to take Fluoxetine Sandoz

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Fluoxetine Sandoz you need to take each day. The usual dose is one capsule taken once a day. Your doctor may increase or decrease your dose depending on your condition.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Fluoxetine Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the capsules whole with a glass of water.

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.

Taking it at the same time each day will help you remember when to take it.

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

How long to take Fluoxetine Sandoz

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

The length of treatment 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 it

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.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering when 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 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Fluoxetine Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you have taken too much Fluoxetine Sandoz, you may feel sick in the stomach, vomit, feel restless, agitated or excited.

While you are taking Fluoxetine Sandoz

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 Sandoz.

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

Tell your doctor if you become pregnant while taking Fluoxetine Sandoz.

Your doctor will discuss the risks and benefits of taking Fluoxetine Sandoz during

pregnancy. If Fluoxetine Sandoz is used during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

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 anti-depressant effect of your medicine 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, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- 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.

Things you must not do

Do not stop taking Fluoxetine Sandoz or lower the dosage without checking with your doctor.

Suddenly stopping Fluoxetine Sandoz 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 Sandoz you are taking before stopping completely.

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

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

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 drive or operate machinery until you know how Fluoxetine Sandoz affects you.

Fluoxetine Sandoz may cause drowsiness in some people.

Do not let yourself run out of Fluoxetine Sandoz over the weekend or on holidays.

Things to be careful of

Be careful driving or operating machinery until you know how Fluoxetine Sandoz affects you.

This medicine may cause drowsiness in some people. If you experience drowsiness, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Fluoxetine Sandoz may have unwanted side effects in some people. 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.

Side effects vary from patient to patient and often lessen with continued use.

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:

- nausea, vomiting
- upset stomach, diarrhoea
- loss of appetite, weight loss, changes in taste, dry mouth
- trouble sleeping, unusual dreams
- nervousness, anxiety
- drowsiness, weakness
- dizziness
- excessive sweating, flushing, chills
- lesions of skin and mucous membrane
- fever and joint aches
- sexual problems
- more frequent urination
- changes in vision.

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

- itching, skin rash or hives
- shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, tongue or other parts of the body
- muscle spasms
- tremors
- twitches
- convulsions or fits
- fast, irregular heart beat
- abnormal bleeding or bruising
- sudden switches of mood to one of overactivity and uninhibited behaviour
- sudden fever
- hallucinations
- loss of coordination
- confusion
- overactive reflexes.

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

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

Other side effects not listed above may also occur in some people.

Children and Adolescents

Headaches are very common side effects.

Weight loss and decreased height gain have been observed in association with the use of Fluoxetine Sandoz in children and adolescent patients. This is similar to other medicines

that belong to the group of medicines called selective serotonin reuptake inhibitors (SSRIs).

After taking Fluoxetine Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Fluoxetine Sandoz 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Fluoxetine Sandoz comes in capsules:

Fluoxetine Sandoz 20mg - green capsule.

Available in blister packs of 28 capsules.

Ingredients

Active ingredient:

Fluoxetine Sandoz 20mg - 20mg fluoxetine (as hydrochloride)

Inactive ingredients:

- pregelatinised maize starch
- dimeticone-350.

Hard-shell capsule:

- gelatin
- titanium dioxide,
- yellow iron oxide
- patent blue.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 634 500

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bay
Auckland 0754
New Zealand
Tel: 0800 354 335

This leaflet was revised in December 2016.

Australian Register Number

20 mg capsules: AUST R 64564 (blisters)