

Fluoxetine AN tablets

Fluoxetine hydrochloride 20 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fluoxetine AN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Fluoxetine AN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Fluoxetine AN is used for

Fluoxetine AN contains the active ingredient fluoxetine hydrochloride. It is used to treat depression.

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.

Depression 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, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive, lack of energy and feelings of guilt.

Fluoxetine AN belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). These medicines work by acting on certain brain chemicals and may help to relieve the physical and emotional symptoms of depression.

Fluoxetine AN is also used to treat a condition known as obsessive compulsive disorder (OCD). The symptoms of OCD vary from patient to patient. Check with your doctor if you need more information.

Your doctor may have prescribed Fluoxetine AN for another reason. Ask your doctor if you have any questions about why Fluoxetine AN has been prescribed for you.

Fluoxetine AN is available only with a doctor's prescription.

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

Before you take Fluoxetine AN

When you must not take it

Do not take Fluoxetine AN if you are allergic to medicines containing fluoxetine or any of the ingredients listed at the end of this leaflet.

Signs of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue or other parts of the body which may cause difficulty in swallowing or breathing, hives, itching or skin rash or fainting.

Do not take Fluoxetine AN if you are taking another medicine called a monoamine oxidase inhibitor (MAOI) such as moclobemide (e.g. Aurorix), phenelzine (e.g. Nardil), selegiline (e.g. Eldepryl) or tranylcypromine (e.g. Parnate), or have been taking a monoamine oxidase inhibitor medicine within the last 14 days.

Taking Fluoxetine AN with a MAOI may cause a serious reaction with a sudden increase in body temperature, shivering, shaking (tremor) muscle stiffness, extremely high blood pressure and rapid breathing or confusion.

Do not take Fluoxetine AN if you are taking pimozone (e.g. Orap). Taking pimozone together with Fluoxetine AN may alter the rhythm of your heart.

Ask your doctor or pharmacist if you are not sure if you have been taking one of these medicines.

Do not take Fluoxetine AN after the expiry date printed on the pack.

Do not take Fluoxetine AN if the packaging is torn or shows signs of tampering or if the capsules do not look right.

If you are not sure whether you should start taking Fluoxetine AN, talk to your doctor.

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines including any other antidepressant medicines
- any other substances, such as foods, preservatives or dyes

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

Fluoxetine AN may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking Fluoxetine AN during pregnancy.

Tell your doctor if you are breast-feeding or wish to breast-feed.

The use of Fluoxetine AN is not recommended during breast-feeding. Fluoxetine AN passes into breast milk and may affect the breast-fed baby.

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 them before you use Fluoxetine AN.

Tell your doctor if you drink alcohol. Your doctor may suggest avoiding alcohol while you are being treated for depression.

Use in children and adolescents (<18 years)

The safety and effectiveness of Fluoxetine AN for the treatment of children and adolescents less than 18 years of age has not been established. Fluoxetine AN is not recommended for use in children and adolescents less than 18 years of age.

Taking other medicines

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

Some medicines and Fluoxetine AN may interfere with each other.

These include:

- other medicines for depression or OCD

- selegiline (e.g. Eldepryl, Selgene). You should stop taking selegiline or any antidepressant medication such as monoamine oxidase inhibitor medicines at least two weeks before starting Fluoxetine AN.
- flecainide, a medicine used to treat irregular heart beat
- tramadol, a medicine used for pain relief
- sumatriptan, a medicine used to treat migraine
- sleeping tablets or sedatives
- medicines for anxiety
- medicines used to control fits
- antipsychotics, e.g. pimozone
- medicines used to prevent blood clots e.g. warfarin
- lithium, a medicine used to treat mood swings and some kinds of mental conditions
- tryptophan
- St John's Wort (*Hypericum perforatum*), a herbal remedy

These medicines may be affected by Fluoxetine AN or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Do not take any monoamine oxidase inhibitor medicines for at least 5 weeks after you have stopped Fluoxetine AN.

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

After you have stopped taking Fluoxetine AN, you should be careful taking other medicines for at least 5 weeks because some of the medicine will still be in your blood stream.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking Fluoxetine AN.

How to take Fluoxetine AN

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 on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many capsules you will need to take each day. This depends on your condition and whether you are taking any other medicines.

The usual dose is one capsule each morning. Your doctor may change your dose depending on how you respond to this medicine.

How to take FLUOXETINE AN

Swallow the prescribed dose of Fluoxetine AN capsules with a full glass of water.

When to take it

It does not matter if you take Fluoxetine AN with or without food.

Take each dose of Fluoxetine AN at about the same time each day.

Taking each dose of Fluoxetine AN at the same time each day will have the best effect. It will also help you to remember when to take the capsules.

How long to take it

The length of treatment with Fluoxetine AN 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 it may take up to four weeks before improvement is apparent. You may need to take Fluoxetine AN for several months or longer.

Continue taking Fluoxetine AN for as long as your doctor recommends.

If you do not start to feel better in about four weeks, check with your doctor.

If you forget to take it

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 the missed dose as soon as you remember, and then go back to taking your tablets 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 have trouble remembering when to take your tablets, 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 you or anyone else may have taken too much Fluoxetine AN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include vomiting, feeling sick in the stomach, restlessness, agitation or excitation.

While you are taking Fluoxetine AN

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Fluoxetine AN.

If you are about to start taking any new medicine, including any medicine that you buy without a prescription, tell your doctor and pharmacist that you are taking Fluoxetine AN.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

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

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 AN 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 your 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.

Tell your doctor immediately if you become pregnant while taking Fluoxetine AN.

Visit your doctor regularly so that your progress can be checked.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take the herbal remedy St. John's Wort while you are being treated with Fluoxetine AN. If you are already taking the herbal remedy, stop taking it and mention it to your doctor at your next visit.

Do not use Fluoxetine AN to treat any other complaints unless your doctor tells you to.

Do not stop taking Fluoxetine AN, or lower the dose, without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of Fluoxetine AN you are using before stopping completely. This may help reduce the possibility of any withdrawal symptoms occurring.

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

Things to be careful of

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

Fluoxetine AN may cause drowsiness or light-headedness in some people and affect mental alertness. Make sure you know how you react to Fluoxetine AN before you drive a car, operate machinery, or do anything else that could be dangerous if you are affected.

Speak to your doctor before drinking alcohol while you are taking Fluoxetine AN.

Although drinking moderate amounts of alcohol is unlikely to affect your response to Fluoxetine AN your doctor may suggest avoiding alcohol while you are being treated for depression.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Adults

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

- difficulty in sleeping
- excessive sweating
- feeling sick, vomiting
- diarrhoea

- loss of appetite, weight loss
- anxiety and nervousness
- drowsiness, tiredness, weakness
- dizziness, light-headedness
- sexual problems
- visual disturbances
- dry mouth, change in sense of taste
- chills and joint aches
- more frequent urination
- erythema multiforme

These side effects are usually mild.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- sudden switch of mood to excitement, overactivity, talkativeness and uninhibited behaviour
- fast, irregular or pounding heart beat, chest pain
- fits, seizures
- cramps, lethargy, confusion
- abnormal bleeding or bruising
- skin rash, hives, itching, peeling or blistering of skin
- shortness of breath or difficulty breathing, swelling of the face, lips or tongue or other parts of the body which may cause difficulty in swallowing or breathing
- muscle spasm, twitches, tremor, muscle stiffness
- fever
- yellowing of the skin or eyes
- shakiness

These side effects are serious. You may need urgent medical attention.

Children and adolescents

Common: Headaches

Less common: Weight loss and decreased height gain have been observed. This is similar to the group of medicines called selective serotonin reuptake inhibitors (SSRI's).

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Fluoxetine AN

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the box or the blister pack they will not keep well.

Keep your Fluoxetine AN in a cool dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink.

Do not leave it in the car or on a windowsill. 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 Fluoxetine AN, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

Fluoxetine AN capsules are available in PVC/PVDC/Al packs of 28 (AUST R 148137).

The capsules are a size 3 gelatin capsule with an opaque light green cap and an opaque ivory body containing a white odourless powder.

Ingredients

Active Ingredient:

Fluoxetine hydrochloride

Each capsule contains 20 mg fluoxetine (as fluoxetine hydrochloride).

Other Ingredients:

- lactose
- cellulose - microcrystalline
- magnesium stearate
- colloidal anhydrous silica
- gelatin
- titanium dioxide
- iron oxide yellow
- quinoline yellow
- indigo carmine

Please read this leaflet carefully before you start taking Fluoxetine AN. You may wish to keep it to read again.

Name and Address of the Sponsor

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