

FLUOX

Fluoxetine hydrochloride Capsules 20 mg

Fluoxetine hydrochloride Dispersible Tablets 20 mg

What is in this leaflet

Please read this leaflet carefully before you start taking FLUOX.

This leaflet answers some common questions about FLUOX.

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 FLUOX against the benefits they expect it will 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 FLUOX is used for

FLUOX is used to treat depression and the anxiety associated with depression, in adults. This 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.

FLUOX is also used to treat bulimia nervosa (eating disorder) and obsessive-compulsive disorder (OCD).

FLUOX may also be used to treat pre-menstrual dysphoric disorder

(PMDD), a severe form of premenstrual syndrome (PMS).

Your FLUOX capsules or dispersible tablets contain fluoxetine hydrochloride. They belong to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs).

SSRIs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

There is no evidence that FLUOX is addictive.

The use of this medicine in children and adolescents under the age of 18 years is not recommended.

Before you take FLUOX

When you must not take it:

Do not take FLUOX if you have an allergy to:

- any medicine containing fluoxetine
- any of the ingredients listed at the end of this leaflet.

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 FLUOX if you are taking:

- another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days
- another medicine that affects the level of a chemical in the brain called serotonin.

Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI or other medicine that affects serotonin in the brain.

If you do take FLUOX while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

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

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 have or have had any of the following medical conditions:

- allergic reaction to any medicine that you have

taken previously to treat your current condition

- kidney or liver disease
- diabetes
- glaucoma
- fits (seizures)
- any heart conditions
- a bleeding disorder or a tendency to bleed more than usual
- electrical shock treatment
- major depressive episodes or other mood disorders (such as bipolar disorder)

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

Your doctor can discuss with you the risks and benefits involved. The general condition of your newborn baby might be affected by the medicine. If your baby has been exposed to this medicine during the last three months of pregnancy it may suffer withdrawal symptoms such as trouble with breathing, fits, feeding difficulties, vomiting, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, constant crying, and sleepiness. If your newborn baby has any of these symptoms, please contact your doctor immediately.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like FLUOX may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Tell your doctor if you drink alcohol. Although drinking alcohol is unlikely to affect your response to FLUOX, your doctor may suggest avoiding alcohol while you are being treated for depression.

If you have not told your doctor about any of the above, tell them before you start taking FLUOX.

Taking other medicines

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

that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking FLUOX.

Some medicines may interfere with FLUOX. These include:

- medicines used to treat depression, obsessive compulsive disorder or premenstrual dysphoric disorder (PMDD) such as monoamine oxidase inhibitors (MAOIs), SNRIs, SSRIs, imipramine, desipramine. You should stop taking MAOIs at least two weeks before starting FLUOX.
- medicines used to relieve anxiety such as diazepam, alprazolam
- sleeping tablets
- sedatives
- medicines used to treat certain mental and emotional conditions, also called antipsychotic medicines such as haloperidol, phenothiazines or clozapine
- medicines used to control fits such as phenytoin or carbamazepine
- opioids such as pethidine, tramadol or dextromethorphan, medicines used to relieve pain
- medicines used for migraines such as sumatriptan or other triptans
- St John's Wort
- lithium, a medicine used to treat mood swings and some types of depression
- tryptophan, a medicine or food supplement used to treat mood disorders
- tamoxifen, a medicine used to treat breast cancer
- medicines that may increase risk of bleeding such as warfarin, aspirin and some anti-inflammatory medicines (NSAIDs)
- oral antidiabetic medicines or insulin.

These medicines may be affected by FLUOX 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 and pharmacist have more information on medicines to be careful with or avoid while taking FLUOX.

Do not start taking other medicines for depression without checking with your doctor. Do this even if you have already stopped taking FLUOX. Monoamine oxidase inhibitors (MAOIs), which are other medicines used for depression, may interfere with FLUOX. You should not start a MAOI for at least 5 weeks after stopping FLUOX.

How to take FLUOX

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 much FLUOX you need to take each day. It is important that you take FLUOX as directed by your doctor. Do not take more than the recommended dose.

The usual daily dose for adults is:

- 20mg to treat depression.
- 60mg to treat bulimia nervosa.
- 20mg to 60mg to treat obsessive-compulsive disorder.
- 20mg continuously throughout the menstrual cycle for premenstrual dysphoric disorder.

Your doctor may increase or decrease your dose depending on your condition. For any condition, the daily dose should not exceed 80mg.

FLUOX should not be used in children and adolescents (under 18 years of age).

How to take it

The capsule(s) should be swallowed whole with a glass of water.

The tablet(s) can either be swallowed with a glass of water or dispersed in water. To disperse your FLUOX tablet, place the tablet(s) in approximately 100mL (½ glass) of water, swirl until tablet disperses, then drink immediately.

When to take it

FLUOX is usually taken in the morning as a single dose.

Take your medicine at about the same time each day.

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

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

How long to take it

Continue taking your medicine for as long as your doctor tells you. It is important to keep taking your medicine even if you feel well. The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return.

For depression, the treatment period will depend on how quickly your symptoms improve. You may not feel better immediately as most antidepressants take time to work. Some of your symptoms may improve in 1 or 2 weeks but it can take 2 to 4 weeks to feel any real improvement. Even when you feel well, you will usually have to take FLUOX for several months or even longer to make sure the benefits will last. If you do not feel better in about four weeks, see your doctor.

For PMDD, initial treatment is limited to six months, after which your condition should be reassessed with your doctor regarding the benefit of continued therapy.

If you forget to take it

If you forget a dose and 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. This may increase the chance of you getting an unwanted side effect.

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

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

While you are taking FLUOX

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FLUOX.

Tell any other doctors, dentists and pharmacists who treat you that you are taking FLUOX.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Your doctor will discuss the risks and benefits of taking FLUOX during pregnancy. If FLUOX 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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

Make sure you do not run out of FLUOX capsules or dispersible tablets.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms:

- anxiety
- agitation
- panic attacks
- insomnia (difficulty sleeping)
- irritability
- hostility (aggressiveness)
- impulsivity
- restlessness or difficulty sitting still
- hypomania, mania (mood of excitement, over-activity and uninhibited behaviour)
- worsening of 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

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 becomes apparent. This is more likely to occur in young adults under 25 years of age.

All mentions of suicide or violence must be taken seriously.

Things you must not do

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

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

Do not stop taking FLUOX or lower the dosage without

checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects, such as dizziness, anxiety, headache, feeling sick, or tingling or numbness of the hands or feet. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

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

Things to be careful of

Be careful driving, operating machinery or performing jobs that need you to be alert until you know how FLUOX affects you. FLUOX may cause drowsiness, dizziness, tiredness and abnormal vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

The combination of FLUOX and alcohol is not recommended. Your doctor may suggest avoiding alcohol while you are being treated for depression.

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.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much FLUOX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, fits or convulsions, changed heartbeat, changes in mood ranging from drowsy to excited.

Side effects

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

This medicine may have unwanted side effects in a few people.

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.

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

- stomach or bowel problems (e.g. nausea, vomiting, diarrhoea, indigestion)
- drowsiness or weakness
- shakiness
- trouble sleeping, unusual dreams
- tiredness
- changes in your sex drive or sexual functions

- loss of appetite or weight loss
- weight gain
- changes in taste
- ringing in the ears
- dry mouth
- nervousness
- anxiety
- increased perspiration or sweating, flushing
- headache
- dizziness, light-headedness
- yawning
- changes in frequency of urination
- changes in amount of urine
- excessive teeth grinding
- unusual hair loss
- sexual problems
- changes in vision
- nose bleeds.

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

- bleeding in the mouth
- memory impairment
- abnormal vision
- impaired concentration or thought processes
- breast enlargement
- clitoris enlargement
- unusual secretion of breast milk
- breast pain
- skin sensitivity after sun exposure.
- lesions of skin and mucous membrane
- fever and joint aches

The above list includes serious side effects that may require medical attention.

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

- palpitations
- sudden or severe headache (Thunderclap headache)
- rash, itching or hives (with or without blistering of the skin)
- swelling of the face, lips, mouth, tongue or throat (which may cause difficulty in swallowing) or other parts of the body

- shortness of breath, wheezing or trouble breathing
- a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- fast, irregular heartbeat
- enlarged lymph nodes
- chills
- any signs of unusual bleeding heavy bleeding after the birth of your baby
- more easily bruising
- difficulties with swallowing
- pain in the throat
- blood in the stools or black, tarry bowel motions
- uncontrollable twitching or jerking movements, muscle spasms, tremors
- involuntary eye movement
- clumsiness and lack of coordination, affecting balance and manner of walking, limb or eye movements and/or speech
- seizures
- sudden mood changes to one of overactivity and uninhibited behaviour
- sudden changes in your energy or activity levels
- sudden fever
- shivering
- rapid changes in vital signs
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm
- distressing restlessness
- overactive reflexes
- extreme agitation, confusion, aggression
- yellowing of the skin and eyes
- dark coloured urine
- hallucinations.

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

On rare occasions, development of a serotonin syndrome or neuroleptic malignant syndrome-like events may occur in association with treatment of fluoxetine treatment, As these syndromes may result in potentially life-threatening conditions, treatment with fluoxetine

and/or the interacting medicine should be discontinued or reduced depending on severity of symptoms,

See your doctor if you experience any of the following when you stop FLUOX treatment:

- dizziness
- tingling or numbness of the hands or feet
- headache
- anxiety
- agitation
- confusion
- sleep disorders
- sensory disturbances
- unusual weakness
- headache
- irritability.

These symptoms are generally not serious and disappear within a few days.

An increased risk of bone fractures has been observed in patients taking this type of medicine.

This medicine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

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. Tell your doctor if you notice any other effects.

Some of these side effects (for example, changes in blood pressure, blood cell counts and others) can only be found when your doctor does tests from time to time to check your progress.

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

After taking FLUOX

Storage

Keep your FLUOX capsules and dispersible tablets in the blister pack until it is time to take them. If you take the capsules or

dispersible tablets out of the pack they may not keep well.

Keep your FLUOX capsules and dispersible tablets in a cool dry place where the temperature stays below 25°C.

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

Product description

Your medicine is in the form of:

- Capsules in blister packs each containing 84 capsules; or
- Dispersible tablets in blister packs each containing 28 or 30 tablets.

What it looks like

FLUOX capsules are hard gelatin capsules with a light green body and a purple cap. They are printed with black ink: "FL20" on the body and "α" on the cap.

FLUOX dispersible tablets are oval, convex with tablets, debossed "FL" breakline "20" on one side and "G" on the other.

Ingredients

Active ingredient:

FLUOX contains fluoxetine hydrochloride equivalent to 20 mg fluoxetine as the active ingredient.

Inactive ingredients:

FLUOX capsules also contain:

- Capsule fill:
 - Lactose monohydrate

- maize starch
- colloidal anhydrous silica
- purified talc
- magnesium stearate

Date of Information

09 August 2023
(Based on datasheet dated 09 August 2023)

Capsule shell:

- shellac
- ethanol
- isopropyl alcohol
- n-butyl alcohol
- propylene glycol
- ammonium hydroxide
- potassium hydroxide
- iron oxide black
- gelatin
- sodium lauryl sulfate
- titanium dioxide
- brilliant blue FCF
- quinolone yellow FCF
- indigo carmine
- erythrosine.

FLUOX capsules contains sulfites and sugars as lactose.

FLUOX dispersible tablets also contain:

- microcrystalline cellulose
- colloidal anhydrous silica
- maize starch
- crospovidone
- saccharin sodium
- magnesium stearate
- menthol
- peppermint oil
- arabic gum
- maltodextrin.

FLUOX dispersible tablets contains saccharin and sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

FLUOX is supplied in New Zealand by:

Viatrix Ltd,
PO Box 11-183,
Ellerslie,
Auckland
www.viatrix.co.nz

Telephone: 0800 168 169