

LOVAN

contains the active ingredient fluoxetine (hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about LOVAN.

It does not contain all 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 LOVAN against the benefits expected 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 LOVAN is used for

LOVAN is used to treat

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

LOVAN 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.

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

Your doctor may have prescribed LOVAN for another reason.

LOVAN is available only with a doctor's prescription.

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

Before you take LOVAN

When you must not take it

Do not take LOVAN if you are allergic to:

- any medicines containing fluoxetine (such as Prozac and Zactin)
- 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 LOVAN 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. Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

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

Do not take LOVAN if you are taking another medicine called pimozone to treat disturbances in thinking, feelings and behaviour.

Taking pimozone together with LOVAN may alter the rhythm of your heart.

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 are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of taking LOVAN during pregnancy. If LOVAN is taken during pregnancy, you should be careful, particularly at the end of your pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn baby after maternal use in the last 3 months of pregnancy. If you take LOVAN near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking LOVAN so they can advise you.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Like many other medicines, LOVAN can pass into breast milk. Your doctor will discuss the risks and

benefits of taking LOVAN when breastfeeding.

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

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

Tell your doctor if you drink alcohol.

Although drinking alcohol is unlikely to affect your response to LOVAN, 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 LOVAN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy with or without a prescription from a 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 LOVAN, 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 LOVAN.

- 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)
- sleeping tablets or sedatives
- medicines used to relieve anxiety

- medicines used to treat certain mental and emotional conditions, also called antipsychotics
- pimozide, a medicine used to treat disturbances in thinking, feelings and behaviour
- medicines used to control fits
- medicines used to prevent blood clots, such as warfarin
- flecainide, a medicine used to treat some heart conditions
- tryptophan, an amino acid available in food supplements and multivitamin preparations
- St John's Wort (Hypericum perforatum), a herbal remedy
- medicines used to relieve pain, such as tramadol
- sumatriptan, a medicine used to treat migraine.

These medicines may be affected by LOVAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking LOVAN.

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

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

How to take LOVAN

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack or bottle, ask your doctor or pharmacist for help.

How much to take

The dose varies from person to person.

Your doctor will tell you how much LOVAN you need to take each day.

The usual starting dose is one tablet or one capsule taken once a day in the morning. Your doctor may change this dose depending on your condition and how you respond to this medicine.

For premenstrual dysphoric disorder (PMDD), LOVAN 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.

How to take it

Capsules - swallow the capsules whole with a glass of water.

Tablets - swallow the tablets whole with a glass of water or disperse it in water first.

To disperse the tablets in water: Swirl the tablet in half a glass of water until it falls apart, then drink it immediately.

When to take it

LOVAN is usually taken as a single dose in the morning. 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 have the best effect. It will also help you remember when to take it.

LOVAN can be taken with or without food.

How long to take it

Continue taking LOVAN for as long as your doctor tells you to.

The length of treatment with LOVAN 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, LOVAN usually 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

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 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.

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 LOVAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking LOVAN

Things you must do

Persons taking LOVAN may be more likely to think about killing themselves or actually trying to do so, especially when LOVAN is first started or the dose is changed. Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

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

Contact your doctor or a mental health professional immediately or go to the nearest hospital for treatment if you or someone you know is demonstrating any of the following warning signs:

- 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 mood or behaviour.

All mentions of suicide or violence must be taken seriously.

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

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

Tell your doctor immediately if you become pregnant while taking LOVAN.

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

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

Things you must NOT do

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

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

Do not stop taking LOVAN, or lower the dose, without checking with your doctor.

Stopping LOVAN suddenly 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 LOVAN you are taking before stopping completely.

Do not take the herbal remedy St John's Wort (*Hypericum perforatum*) while you are being treated with LOVAN.

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 let yourself run out of LOVAN over the weekend or on holidays.

Things to be careful of

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

LOVAN 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 LOVAN.

Like all other medicines, LOVAN may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Side effects vary from person to person and often go away with continued use.

Do not be alarmed by the following list of possible 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
- anxiety, nervousness
- 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.

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

- 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.

Children and Adolescents

Headaches are very common side effects.

Weight loss and decreased height gain have been observed in association with the use of LOVAN in children and adolescent patients. This is similar to other medicines that belong to the group of medicines called selective serotonin reuptake inhibitors (SSRIs).

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.

After taking LOVAN

Storage

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

If you take the tablets or capsules out of the pack they may not keep as well.

Keep LOVAN tablets in a cool, dry place where the temperature stays below 25°C.

Keep LOVAN capsules in a cool, dry place where the temperature stays below 30°C.

Do not store LOVAN or any other medicine in the bathroom or near a sink. Do not leave LOVAN in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep LOVAN 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 LOVAN, 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

LOVAN is available as tablets and capsules.

LOVAN tablets are oval, white, scored and marked 4400.

LOVAN capsules are green and marked 20.

LOVAN capsules and tablets are available in packs of 28.

Ingredients

The active ingredient in LOVAN is fluoxetine (as fluoxetine hydrochloride).

Each LOVAN tablet contains 20 mg of fluoxetine as the active ingredient.

The tablets also contain:

- microcrystalline cellulose
- saccharin sodium
- mannitol
- sorbitol
- colloidal anhydrous silica
- maize starch
- sodium stearyl fumarate
- crospovidone
- peppermint flavour

- aniseed flavour.

Each LOVAN capsule contains 20 mg of fluoxetine as the active ingredient.

The capsules also contain:

- maize starch
- dimeticone 350
- gelatin
- indigo carmine
- quinoline yellow
- edible black ink.

Supplier

LOVAN is supplied by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.viatris.com.au
Phone: 1800 274 276

Australian registration numbers:

LOVAN tablets - AUST R 61080

LOVAN capsules - AUST R 54700

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