

Movox

contains the active ingredient fluvoxamine maleate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions about Movox.

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 Movox against the benefits expected for you.

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

Please read this leaflet carefully and keep it with your medicine.

You may need to read it again.

What Movox is used for

Movox is used to treat:

- Depression in adults
- Obsessive Compulsive Disorder (OCD) in children aged 8 years and older, adolescents, and adults.

Movox belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

SSRIs are thought to work by acting on chemicals in the brain called amines, which are involved in controlling mood. Movox corrects this chemical imbalance and helps to relieve the symptoms of the above conditions.

Tell your doctor immediately, or go to the nearest hospital, if you have any distressing thoughts or experiences during the initial

period of starting Movox, or at any other time.

Also, contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

Like other medicines of this type, Movox will not relieve your symptoms straight away. People generally start feeling better in a few weeks or so.

Occasionally, the symptoms of depression or other psychiatric (mental) conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full antidepressant effect of your medicine becomes apparent.

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

Your doctor may have prescribed Movox for another reason.

Movox is not approved for use in children and adolescents below:

- 18 years of age for the treatment of depression
- 8 years of age for the treatment of Obsessive Compulsive Disorder.

The safe use and effectiveness of Movox in treating the above conditions, for this age group, has not been established.

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

Before you take Movox

When you must not take it

Do not take Movox if you have an allergy to any medicines containing fluvoxamine maleate or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Movox if you are taking another medicine for depression known as a monoamine oxidase inhibitor (MAOI).

Movox can only be started if you have stopped taking:

- tranylcypromine (e.g. Parnate) and phenelzine (e.g. Nardil) for at least 14 days
- moclobemide (eg. Aurorix, Arima) for at least 1 day.

Taking Movox with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Do not take Movox if you are taking cisapride (e.g. Prepulsid), a medicine used to treat stomach reflux.

Combining Movox with cisapride may cause serious side effects such as an abnormal heart rhythm.

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

Do not take Movox if you are breastfeeding or plan to breastfeed.

Movox passes into breast milk and may affect your baby.

Do not take Movox if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Movox if the packaging shows signs of tampering or if the tablets do not look right.

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.

There have been reports of some babies experiencing complications immediately after delivery. Your doctor will discuss the possible risks and benefits of taking Movox during pregnancy.

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

- liver problems
- kidney problems
- epilepsy, seizures or fits
- diabetes
- bleeding problems
- thoughts of suicide or self-harm.

Your doctor may want to take special care if you have any of these conditions.

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

Taking other medicines

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

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

Some medicines and Movox may interfere with each other. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat depression. Do not take Movox with MAOIs. Movox can only be started after you have stopped taking:
 - tranylcypromine (e.g. Parnate) and phenelzine (e.g. Nardil) for at least 14 days
 - moclobemide (e.g. Aurorix, Arima) for at least 1 day
- cisapride (e.g. Prepulsid), a medicine used in the treatment of stomach reflux. Do not take Movox with cisapride.
- other antidepressants, including other SSRIs and tricyclic antidepressants such as imipramine (eg. Tofranil), amitriptyline (eg. Endep), clomipramine (eg. Anafranil, Placil)
- medicines used to treat mental illnesses including schizophrenia, such as clozapine (e.g. Clozaril) and olanzapine (e.g. Zyprexa), thioridazine (e.g. Melleril), haloperidol (e.g. Serenace)
- St John's Wort (Hypericum perforatum), a herbal remedy used for depression
- lithium (eg. Lithicarb), a medicine used to treat mood swings and some types of depressions
- medicines for epilepsy, such as carbamazepine (eg. Teril, Tegretol) or phenytoin (e.g. Dilantin)
- medicines to prevent blood clots, such as warfarin (e.g. Coumadin, Marevan)
- phentermine (e.g. Duromine) used in weight reduction programs
- sumatriptan (e.g. Imigran), a medicine used to relieve of migraines
- tramadol (e.g. Tramal), aspirin and NSAIDs (non-steroidal anti-inflammatory drugs), medicines used for pain relief
- tryptophan, an amino acid found in sports and dietary supplements
- benzodiazepines, medicines used as sedatives or to treat anxiety such as alprazolam (e.g. Xanax, Kalma), diazepam (e.g. Valium, Antenex), triazolam (e.g. Halcion), midazolam (e.g. Hypnovel)
- theophylline (e.g. Nuelin), a medicine used to treat asthma
- propranolol (e.g. Inderal, Deralin), a medicine used to treat certain heart conditions and prevent migraines
- methadone, a medicine used to relieve strong pain and opioid drug dependence
- mexiletine (e.g. Mexitil), a medicine used in the management of irregular heart beats
- cyclosporin, a medicine used to help prevent organ transplant rejection or to treat certain problems with the immune system.

These medicines may be affected by Movox 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 (including herbal and other remedies) can interact with Movox and increase the risk of side effects, some of which can be potentially life threatening.

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

How to take Movox

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, ask your doctor or pharmacist.

Movox contains the active ingredient fluvoxamine. It must not be confused with medicines such as Lovan, Zactin and Prozac, which contain the active ingredient fluoxetine.

How much to take

The dose varies from person to person.

The dose will depend on your age, the condition being treated and any medicines you are taking.

Depression

For adults, the usual starting dose is 50 mg once a day. Your doctor may then gradually increase this dose depending on how you respond to this medicine. The maximum daily dose is 300 mg per day.

Movox is not approved for use in children and adolescents below 18 years of age in the treatment of depression, as the safe use and effectiveness has not been established for this age group.

Obsessive Compulsive Disorder (OCD)

For adults, the usual starting dose is 50 mg once a day. Your doctor may then gradually increase this dose depending on how you respond to this medicine. The maximum daily dose is 300 mg per day.

For children and adolescents 8 to 17 years of age, the usual starting dose is 25 mg once a day at bedtime. The doctor may then gradually increase this dose depending on how you respond to this medicine. The maximum daily dose is 200 mg per day.

Movox is not approved for use in children and adolescents below 8

years of age in the treatment of OCD, as the safe use and effectiveness has not been established for this age group.

How to take it

Swallow Movox tablets whole with a full glass of water.

Do not chew the tablets.

When to take it

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.

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 it as soon as you remember, then go back to taking it 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 or have any questions, ask your doctor or pharmacist for help.

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 your nearest hospital if you think you or anyone else may have taken too much Movox.

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

You may need urgent medical attention.

If you take too much Movox you may feel sick (nauseous), vomit or have diarrhoea. You may also feel drowsy, dizzy or faint, have a fast or slow heartbeat or have fits.

How long to take it

Keep taking Movox for as long as your doctor recommends.

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 don't feel better right away.

Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take Movox for several months or even longer to make sure the benefits last.

Do not stop taking Movox unless your doctor tells you to, even if you feel better.

While you are taking Movox

Things you must do

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

All mentions of suicide or violence must be taken seriously.

Immediately contact your doctor or a mental health professional, or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

Patients and caregivers should be alert and monitor for these effects.

Be especially careful of any suicidal thoughts or other mental/

mood changes in the first few months of taking Movox or when the dose is changed.

These effects are more likely to occur in children, adolescents and young adults under 25 years, including those not being treated for depression.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may want to take some blood tests and check your heart, blood pressure and weight (children) from time to time.

Tell your doctor immediately if you become pregnant while taking Movox. You should not stop taking your tablets until you have spoken to your doctor.

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

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

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

Things you must not do

Do not suddenly stop taking Movox or change the dose, without first checking with your doctor. Do not let yourself run out of medicine over weekends or holidays.

Stopping Movox suddenly or reducing the dose too quickly may cause discontinuation symptoms such as headache, nausea, dizziness, and anxiety.

Your doctor will tell you how to gradually reduce the amount of Movox you are taking before stopping completely.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Do not use Movox to treat any other conditions unless your doctor tells you to.

Things to be careful of

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

Movox may cause drowsiness, dizziness or sleepiness in some people and affect alertness. If you experience any of these, do not drive, operate machinery or do anything else that could be dangerous.

It is recommended you do not drink alcohol while taking Movox.

Be careful drinking large amounts of caffeine-containing beverages (eg. coffee, tea) while taking Movox.

Movox may increase the amount of caffeine in the body, causing caffeine-related side effects such as tremor or shaking, a fast or irregular heart beat, nausea (feeling sick), insomnia (trouble sleeping) or restlessness.

After you have stopped taking Movox, you should still be careful for 1 or 2 weeks.

Some of the medicine may still be in your system.

Side effects

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

Movox helps most people with their condition, but it may have unwanted side effects in some people.

All medicines 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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist any questions you may have.

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

- unusual tiredness or weakness
- nausea, vomiting,
- dizziness, drowsiness, difficulty sleeping
- headache
- dry mouth
- constipation, diarrhoea
- heartburn
- loss of appetite
- faster heart beat
- sweating
- trembling or shaking.

The above list includes the milder side effects of your medicine, which are usually short-lived.

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

- agitation, anxiety, confusion, hallucinations, nervousness
- muscle twitching, uncontrolled or increase in body movements
- unusual bleeding or bruising under the skin.

The side effects listed above are serious and may need urgent medical attention.

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

- signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- convulsions, fits or seizures
- vomiting blood, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea.

The above list includes very serious side effects, which are uncommon or rare. You may need urgent medical attention or hospitalisation.

Other side effects observed more frequently in children are:

- abnormal thoughts or behaviour
- cough
- increased period pain
- nose bleeds
- increased restlessness
- infection and sinusitis.

Tell your doctor if you notice anything else that is making you feel unwell, including any suicidal thoughts or other mental/mood changes (see Things you must do).

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

After using Movox

Storage

Keep Movox 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.

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

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

Keep your tablets in a cool, dry place where it stays below 25°C.

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

Do not leave Movox in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Movox, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Movox is available in 2 strengths:

- Movox 100 mg - oval, biconvex, scored, white film-coated tablet, marked "S" on one side and "313" over scoreline over "313" on the other.
- Movox 50 mg - oval, biconvex, scored, white film-coated tablet, marked "S" on one side and "291" over scoreline over "291" on the other.

Each packs contains 30 tablets.

Ingredients

The active ingredient in Movox tablets is fluvoxamine maleate.

- Each Movox 100 mg tablet contains 100 mg of fluvoxamine maleate.
- Each Movox 50 mg tablet contains 50 mg of fluvoxamine maleate.

The tablets also contain the following inactive ingredients:

- mannitol
- maize starch
- pregelatinised potato starch
- sodium stearyl fumarate
- colloidal anhydrous silica
- hypromellose
- macrogol 6000
- talc
- titanium dioxide CI77891 (E171).

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

Sponsor

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Movox 100 - AUST R 90059

Movox 50 - AUST R 90058

This leaflet was prepared on
20 October 2010.