

MOVOX[®]

fluvoxamine maleate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about MOVOX. 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 risks and benefits. Your doctor has weighed the risks of you taking MOVOX against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MOVOX is used for

MOVOX belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs) and is used for treatment of the conditions listed below, or your doctor may prescribe MOVOX for another reason.

Depression

MOVOX is used to treat depression in adults only. It is not recommended for treatment of this condition in children and adolescents as the safety and effectiveness of this medicine, when used for depression in this age group, have not been established.

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. It can affect 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 for no reason.

Obsessive compulsive disorder (OCD)

MOVOX is also used to treat a condition known as obsessive compulsive disorder (OCD) in adults and children eight years of age or older.

People with OCD can have two types of symptoms - obsessions and compulsions. Obsessions are unwanted repeated thoughts or feelings, which are ongoing. Compulsions are the need to repeat actions over and over. The symptoms of OCD can vary from patient to patient.

Both of these conditions are thought to be caused by a chemical imbalance in parts of the brain. MOVOX corrects this chemical imbalance and may help relieve the symptoms of depression and OCD.

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

Your doctor may have prescribed it for another purpose.

There is no evidence that this medicine is addictive.

MOVOX is only available 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 medicine containing fluvoxamine
- 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 MOVOX if:

- you are taking another antidepressant medicine called a monoamine oxidase inhibitor (MAOI) (e.g. moclobemide and selegiline) or have been taking it within the last 14 days. Taking MOVOX with these types of medicines may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.
- you are taking any of the following medicines:
 - cisapride
 - tizanidine
 - ramelteon

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

Do not breast-feed if you are taking this medicine.

The active ingredient in MOVVOX passes into breast milk and there is a possibility that your baby may be affected.

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
- you have, or have had, any other medical conditions, including:
 - bipolar disorder or mania
 - any other mental illness
 - liver problems
 - kidney problems
 - epilepsy or convulsive disorders
 - a history of bleeding disorders
 - diabetes
 - glaucoma, an eye condition

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.

You should avoid drinking alcohol while taking MOVVOX.

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

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 medicines and MOVVOX may interfere with each other. Some of these include:

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs), such as moclobemide and selegiline. Taking MOVVOX with or within 14 days of stopping a MAOI may cause a serious reaction with sudden increase in body temperature, extremely high blood pressure, and convulsions
- medicines used to treat depression, obsessive compulsive disorder, anxiety disorders, mood disorders, or other psychoses such as sertraline, amitriptyline, clomipramine, imipramine, clozapine, olanzapine, quetiapine, lithium and haloperidol
- medicines used for strong pain management such as tramadol
- some benzodiazepine medicines such as alprazolam, triazolam, midazolam and diazepam
- medicines called NSAIDs used to relieve pain, swelling and inflammation including arthritis such as ibuprofen and diclofenac
- medicines used to help control epilepsy such as carbamazepine or phenytoin
- medicines used to treat migraine such as sumatriptan, zolmitriptan or eletriptan
- medicines used to help stop the blood from clotting such as warfarin, aspirin or clopidogrel
- cisapride, a medicine used to treat gastroesophageal reflux disease
- tizanidine, a medicine used as a muscle relaxant
- ramelteon, a medicine used to treat insomnia

- terfenadine and astemizole, medicines used to treat symptoms of allergic reaction
- phentermine, a medicine used to assist weight loss
- theophylline, a medicine used to treat breathing conditions such as asthma
- ciclosporin, a medicine used for immunosuppression
- methadone, a medicine used for opioid detoxification
- any herbal remedies that include St John's Wort or tryptophan

There are many other medicines not listed here which could interfere with MOVVOX and vice versa. Always tell your doctor or pharmacist that you are taking MOVVOX before taking a new medication or complementary health product. These medicines may be affected by MOVVOX or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Some combinations of medicines (including herbal and other remedies) can interact with MOVVOX 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 avoid while taking MOVVOX.

How to take MOVVOX

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

These directions 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 or pharmacist will tell you how many MOVVOX tablets to

take each day. These will be printed on the pharmacy label on the container.

To treat depression:

Adults: The usual starting dose is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved up to a maximum of 300 mg per day. If a daily dose of more than 150 mg is needed, the dose should be divided and taken 2 or 3 times per day.

To treat OCD:

Adults: The usual starting dose is 50 mg each day, but your doctor may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved up to a maximum of 300 mg per day. If a daily dose of more than 150 mg is needed, the dose should be divided and taken 2 or 3 times per day.

Children & Adolescents: The usual starting dose is 25 mg each day. The doctor will probably adjust the dose until the desired response is achieved.

How to take it

Swallow the tablet with a full glass of water. Do not chew the tablets.

Take MOVVOX with or without food.

If you have any concerns about how to take this medicine, ask your doctor or pharmacist.

How long to take it

Even if you feel better, continue taking your medicine until your doctor tells you to stop.

The length of treatment will depend on how quickly your symptoms improve. Most antidepressants 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 MOVVOX for several months or

even longer to make sure the benefits are maintained.

In general, antidepressant medication should be continued for at least 6 months following recovery of a depressive episode.

This medicine should not be stopped abruptly (unless you develop a severe side effect to MOVVOX (see 'Side Effects' below)).

If your MOVVOX treatment needs to be stopped, your doctor or pharmacist will provide you with instructions to reduce the dose gradually over a period of at least one or two weeks.

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

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 Australia or 0800 764 766 New Zealand), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much MOVVOX.

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

You may need urgent medical attention. The most common symptoms are nausea (feeling sick), vomiting and diarrhoea. You could also experience drowsiness and dizziness, rapid or irregular heartbeats, tremors or feel faint.

If possible, show the doctor the pack of tablets.

While you are taking MOVVOX

Things you must do

If you are about to start or stop any medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, tell your doctor and pharmacist that you are taking MOVVOX.

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

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 tablets are not helping your condition.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.

This will help your doctor to determine the best treatment for you.

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

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 and blood pressure from time to time. This helps prevent unwanted side effects.

Things to be careful of

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

Care givers should consider all mentions of suicide or violence, which must be taken seriously.

Immediately contact your doctor or go to the nearest hospital for

help if you or someone you know who are being treated for depression (or for any other condition) are demonstrating any of the warning signs of suicide.

Families and caregivers of children and adolescents who are taking MOVVOX should be especially watchful of the warning signs associated with suicide listed below.

The warning signs include:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- Mood changes such as an increase in aggressive or unusual behaviour, anxiety, irritability, agitation, panic attacks, insomnia, impulsivity, restlessness, or worsening of depressive symptoms.

Be especially careful of any suicidal thoughts or other mental/mood changes in the first few months of taking MOVVOX or when the dose is changed.

There is a greater risk of suicide in people with history of suicidal thoughts prior to starting MOVVOX, and in those aged less than 24 years, including those not being treated for depression.

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

It may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

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

You should minimise your intake of caffeine-containing beverages (e.g. coffee or tea) while taking MOVVOX.

MOVVOX can increase the effects of caffeine. People having large amounts of caffeine whilst on

MOVVOX can experience tremor (shaking), palpitations (fast or irregular heart beat), nausea, restlessness and trouble or inability to sleep.

Older people may become confused when taking MOVVOX. Families and carers should be aware of this. Special care may be needed.

You should be careful for 1 or 2 weeks after stopping this medicine, because it will still be in your blood stream.

Things you must not do

Do not stop taking MOVVOX, increase or lower the dose, without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Suddenly stopping it may cause headache, nausea, dizziness and anxious feelings.

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 MOVVOX to treat any other complaints unless your doctor tells you to.

Side Effects

Check with your doctor as soon as possible if you do not feel well while you are taking MOVVOX, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, MOVVOX can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

You may not experience any of them.

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

- nausea, vomiting, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, dry mouth,
- drowsiness, difficulty sleeping, dizziness, nervousness, feeling anxious, headache,
- muscle weakness, muscular pains, pins and needles,
- abnormal taste,
- faster heartbeat, sweating,
- weight gain, weight loss,
- restlessness, pacing, swinging of the legs while seated, rocking from foot to foot

Tell your doctor immediately if you notice any of the following:

- Muscle spasms or twitches
- Significant bleeding or bruising

Stop taking MOVVOX and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if any of the following happens:

- Allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing
- Sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- Sudden increase in body temperature, severe convulsions
- Fast heartbeat, sweating, racing thoughts and restlessness.

These are very serious, though rare, side effects.

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 to be careful of').

Other side effects not listed above may occur in some patients.

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

After using MOVOX

Storage

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

Keep the pack in a cool, dry place (below 25°C). Do not store MOVOX in the bathroom, near a sink or leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep MOVOX where young 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 MOVOX, or the tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

MOVOX 50 mg tablets are round, biconvex, white film coated tablets marked with "291" on either side of the score line and no embossing on the other side. Packs of 30 tablets.

MOVOX 100 mg tablets are oval, biconvex, white film coated tablets marked with "313" on either side of the score line, with no embossing on the other side. Packs of 30 tablets.

Ingredients

Active ingredient:

- MOVOX 50 mg tablets - fluvoxamine maleate 50 mg
- MOVOX 100 mg tablets - fluvoxamine maleate 100 mg

Inactive ingredients:

- mannitol
- maize starch
- pregelatinised potato starch
- sodium stearyl fumarate
- colloidal anhydrous silica
- hypromellose
- macrogol 6000
- purified talc
- titanium dioxide

MOVOX does not contain lactose, sucrose, gluten, or tartrazine.

Sponsor

MOVOX is manufactured in France and supplied in Australia by:

Mylan Health Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
Australia
www.mylan.com.au
Phone: 1800 314 527

This leaflet was prepared in April 2018.

Australian Registration Number:

50 mg: AUST R 90058

100 mg: AUST R 90059

Version 1