

Voxam®

fluvoxamine maleate tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Voxam.

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 this medicine 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 VOXAM IS USED FOR

Voxam contains fluvoxamine. It belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs).

This medicine is used to treat depression in adults and a condition known as "Obsessive Compulsive Disorder" (OCD) in adults and children eight years of age or older. Both of these conditions are thought to be caused by a chemical imbalance in parts of the brain.

Voxam corrects this chemical imbalance and may help relieve the symptoms of depression and OCD.

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 caused by a chemical

imbalance in the brain 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.

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.

Voxam is approved for the uses listed above. However, your doctor may prescribe this medicine for another use.

Ask your doctor if you have any questions about why it was prescribed for you.

Voxam is not recommended for use in children (under the age of 8), as the safety and effectiveness of Voxam in this age group have not been established.

There is no evidence that this medicine is addictive.

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

BEFORE YOU TAKE VOXAM

When you must not take it

Do not take this medicine if you have an allergy to:

- fluvoxamine, the active ingredient, or to any of the ingredients listed at the end of this leaflet under 'PRODUCT DESCRIPTION'

- any other similar medicines.

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 this medicine if:

- you are taking another antidepressant medicine called an irreversible monoamine oxidase inhibitor (MAOI) or the reversible MAOI (RIMA) called moclobemide or have been taking these within the last 14 days. Taking this medicine with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

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

- you are taking cisapride, linezolid or tizanidine.

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, contact 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:

- liver problems
- kidney problems
- epilepsy
- a history of bleeding disorders
- glaucoma
- bipolar mood disorder
- diabetes.

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

The active ingredient in Voxam passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you drink alcohol.

You should avoid drinking alcohol while taking this medicine.

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

Taking other medicines

Tell your doctor or pharmacist 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 Voxam may interfere with each other. These include:

- aspirin and NSAIDs
- any medications used to treat depression, obsessive compulsive disorder, anxiety disorders or other psychoses.

You should also tell your doctor if you are taking tryptophan, sumatriptan, phentermine, tramadol, lithium, any herbal products containing St. John's Wort, warfarin, clomipramine, amitriptyline, imipramine, clozapine, olanzapine, quetiapine, tacrine, theophylline, methadone,

mexiletine, thioridazine, propranolol, ropinirole, terfenadine, astemizole, cisapride, linezolid, alprazolam, triazolam, midazolam, diazepam, haloperidol, cyclosporin, carbamazepine or phenytoin.

These medicines may be affected by Voxam, or may affect how well it works. You may need 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 Voxam and increase the risk of side effects, some of which can be potentially life-threatening.

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

HOW TO TAKE VOXAM

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, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you will need to take each day. These will be printed on the pharmacy label on the container.

Adults:

Your doctor will normally tell you to start taking 50mg each day, but may adjust the number of tablets or the strength of the tablets you are taking until the desired response is achieved.

Children (8 years and above) and adolescents:

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Voxam may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

Take the tablets with or without food.

How long to take Voxam

Even if you feel better, continue taking your medicine for as long as your doctor tells you.

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 Voxam for several months or even longer to make sure the benefits are maintained.

If your doctor tells you to stop taking Voxam, do not stop abruptly. The dose should be reduced gradually over a period of at least 1 or 2 weeks.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that 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 Poisons Information Centre (telephone 13 11 26) for advice, or go to Accidents and Emergency at your nearest hospital if you think you or anyone else may have taken too much Voxam. 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, or feel faint.

WHILE YOU ARE TAKING VOXAM

Things you must do

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

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

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

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.

Keep all of your doctor's appointments 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 you must not do

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

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

Do not stop taking Voxam 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 Voxam may cause headache, nausea, dizziness, anxious feelings, sleep disturbances, sense disturbances, irritability, confusion, sweating, palpitations or tremor.

Things to be careful of

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 go to the nearest hospital for help if you or someone you know are being treated for depression (or for any other condition) and are demonstrating any of the warning signs of suicide.

Families and caregivers of children and adolescents who are taking Voxam 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, irritability, agitation or worsening of depressive symptoms.

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

These effects are more likely to occur in people aged less than 24 years including those not being treated for depression.

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

This medicine 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 Voxam, 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 and tea) while taking Voxam. Large amounts of caffeine may result in side effects such as tremor (shaking), palpitations (fast or irregular heart beat), nausea (feeling sick), insomnia (trouble or inability to sleep) or restlessness.

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

After you have stopped taking Voxam, you should still be careful for 1 or 2 weeks because some of the medicine will still be in your blood stream.

SIDE EFFECTS

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

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

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

- nausea, vomiting, drowsiness, difficulty sleeping, dizziness, nervousness, feeling anxious, dry mouth, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, muscle weakness, pins and needles, abnormal taste, headache, faster heart beat, sweating, weight gain, weight loss or unusual bruising.

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

- muscle spasms or twitches.

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

- allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty breathing or swallowing
- sudden onset of prolonged muscular spasm, affecting the eyes, head, neck and body
- sudden increase in body temperature, severe convulsions
- fast heart beat, 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 or pharmacist 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 also occur in some people.

AFTER TAKING VOXAM

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Voxam or any other medicine in a bathroom or near a sink. Do not leave it in the car or on window sills.

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any that is left over.

PRODUCT DESCRIPTION

What it looks like

Voxam comes in two strengths:

Voxam 50mg - white, round, biconvex film-coated tablets marked "291" on one side, with a line in the middle, making them easy to break in half if necessary.

Voxam 100mg - white, oval shaped, biconvex film-coated tablets marked "313" on one side, with a line through the middle, making them easy to break in half if necessary.

Available in blister packs of 30 tablets.

Ingredients

Active ingredient:

- Voxam 50mg - 50mg fluvoxamine maleate.
- Voxam 100mg - 100mg fluvoxamine maleate.

Inactive ingredients:

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

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

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 634 500

This leaflet was revised in January 2016.

Australian Registration Numbers

50mg tablet: AUST R 111781
(blisters)

100mg tablet: AUST R 111782
(blisters)