

## 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) and is used for treatment of the conditions listed below, or your doctor may prescribe Voxam for another reason.

#### Depression

This medicine 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)

Voxam 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.

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

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

Your doctor may have prescribed it for another purpose.

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 anti-depressant medicine called a monoamine oxidase inhibitor (MAOI) (eg. moclobemide and selegiline) or have been taking it within the last 14 days. Taking this medicine 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 pimozone, cisapride, ramelteon or tizanidine.

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

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

The active ingredient in Voxam 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, 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
- a history of bleeding disorders
- epilepsy or convulsion disorders
- glaucoma
- bipolar mood disorder or mania
- any other mental illness
- diabetes
- glaucoma, an eye condition

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

Your doctor can discuss with you the risks and benefits involved.

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:

- other medicines for the treatment of depression called

monoamine oxidase inhibitors (MAOIs), such as moclobemide and selegiline. Taking Voxam 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

- medications used to treat depression, obsessive compulsive disorder, anxiety disorders or other psychoses such as sertraline, amitriptyline, clomipramine, imipramine, clozapine, olanzapine, quetiapine, lithium, pimozide 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 Voxam and vice versa. Always tell your doctor or pharmacist that you are taking Voxam before taking a new medication or complementary health product. 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.

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## HOW TO TAKE VOXAM

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**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.

### **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 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 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.

**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.

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 Voxam (see 'Side Effects' below)).**

If your Voxam 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 1 or 2 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 that 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) 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 irregular heartbeat, tremors or feel faint.

**If possible, show the doctor the pack of tablets.**

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## WHILE YOU ARE TAKING VOXAM

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### *Things you must do*

**If you are about to be started on any new 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 Voxam.**

**Tell all doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**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.

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

**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 and anxious feelings,.

### *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 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, 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 Voxam or when the dose is changed.**

There is a greater risk of suicide in people with history of suicidal thoughts prior to starting Voxam, and those 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.**

Voxam can increase the effects of caffeine. People having large amounts of caffeine whilst on Voxam may experience tremor (shaking), palpitations (fast or irregular heart beat), nausea (feeling sick), restlessness and trouble or inability to sleep.

Older people may become confused when taking Voxam. 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.**

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## SIDE EFFECTS

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**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, stomach pain, constipation, diarrhoea, heart burn, loss of appetite, dry mouth
- drowsiness, difficulty sleeping, dizziness, nervousness, feeling anxious, headache
- muscle weakness, pins and needles, muscular pain
- 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 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
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- severe skin reaction with painful red areas, large blisters and peeling skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell.

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.

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## AFTER TAKING VOXAM

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### *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.**

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## PRODUCT DESCRIPTION

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### *What it looks like*

Voxam comes in two strengths:

Voxam 50 mg - 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 100 mg - 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 50 mg - 50 mg fluvoxamine maleate
- Voxam 100 mg - 100 mg 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 726 369

This leaflet was revised in May 2020.

### **Australian Registration Numbers**

50 mg tablet: AUST R 111781  
(blisters)

100 mg tablet: AUST R 111782  
(blisters)