

FAVERIN Tablets

fluvoxamine maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about FAVERIN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

Please read this leaflet before you start taking FAVERIN.

If you are helping someone else take FAVERIN, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FAVERIN against the benefits they expect it will have for you.

If you have any concerns about taking FAVERIN, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with your medicine.

You may need to read it again.

What FAVERIN is used for

FAVERIN belongs to a family of medicines known as selective serotonin reuptake inhibitors (SSRIs).

It 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. FAVERIN 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. Check with your doctor if you need more information.

FAVERIN is approved for the uses listed above. However, your doctor may prescribe this medicine for another use. If you would like more information, ask your doctor.

It is not recommended for use in children and adolescents (under the age of 18) for the treatment of depression, as the effectiveness of FAVERIN in this age group have not been established.

It is not recommended for use in children (under the age of 8) for the treatment of OCD, as the safety and effectiveness of FAVERIN in this

age group have not been established.

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

Before you take it

When you must not take it

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

Do not take it if you are taking another anti-depressant medicine called an irreversible monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days.

Examples of these medicines are NARDIL™ (phenelzine) and PARNATE™ (tranylcypromine).

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

If you have taken a "reversible monoamine oxidase inhibitor" such as AURORIX™ (moclobemide), it is all right to start taking FAVERIN the next day. **Do not take FAVERIN at the same time as you take AURORIX™, and always follow your doctor's instructions carefully.**

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

Do not take it if you are taking a medicine called PREPULSID™ (cisapride).

Do not take it if you are pregnant.

The safety of FAVERIN in pregnancy is uncertain.

Do not take FAVERIN if you are breast-feeding.

Like many other medicines, it can pass into breast milk and may affect your baby.

Do not take it if the packaging is torn or shows signs of tampering or if the tablets do not look right.**Do not take it 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.

If you are not sure whether you should start taking FAVERIN, contact your doctor.*Before you start to take it***You must tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.****Tell your doctor if you have, or have had any other health problems or 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 intend to become pregnant.

Your doctor will discuss with you the risks and benefits of taking FAVERIN when pregnant.

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

Your doctor will discuss the risks and benefits of taking FAVERIN when breastfeeding.

Tell your doctor if you drink alcohol.

You should avoid drinking alcohol while taking FAVERIN.

Taking other medicines

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

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 may interfere with FAVERIN. These include:

- other medicines for the treatment of depression called monoamine oxidase inhibitors (MAOIs), such as moclobemide and selegiline. Taking FAVERIN within 14 days of stopping 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
- medicine 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 medicines 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

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

These medicines may be affected by the medicine 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.

Your doctor or pharmacist would have more information on medicines to avoid while taking FAVERIN.

How to take it

FAVERIN contains fluvoxamine. It must not be confused with LOVAN®, which contains fluoxetine. Please contact your doctor or pharmacist if you are not sure.

Take FAVERIN exactly as your doctor has prescribed.*How much to take*

Adults: Your doctor will normally tell you to start taking 50 mg each day, but will probably adjust the number of tablets or the strength of the tablets you are taking until the medicine is effective.

Children & Adolescents: The usual starting dose is 25 mg each day. The doctor will probably adjust the dose until the medicine is effective. FAVERIN should not be used to treat OCD in children younger than 8 years of age.

It should not be used to treat depression in children and adolescents younger than 18 years of age.

You may experience some nausea (feeling sick) at first, but this usually disappears after the first 2 weeks of treatment. Make sure you tell your doctor if you feel sick or notice any other symptoms while you are taking FAVERIN.

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 box, ask your doctor or pharmacist for help.

How to take it

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

How long to take it

The length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you do not 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 FAVERIN for several months or even longer to make sure the benefits will last. Continue taking your tablets until your doctor tells you to stop.

If your doctor tells you to stop taking FAVERIN and if you are taking a dose of two tablets (200 mg) or more per day, do not stop treatment abruptly. You should

reduce the dose by one tablet (100 mg) every three days.

Do not stop using it unless your doctor tells you to – even if you feel better.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period 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.

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) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much FAVERIN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these

places handy. Take the pack of tablets with you to the doctor or hospital.

The most common symptoms are nausea (feeling sick), vomiting and diarrhoea. You could also experience drowsiness and dizziness, or feel faint.

If you are not sure what to do, contact your doctor or pharmacist.

Instructions for doctor: symptomatic treatment should be employed.

While you are using FAVERIN

Things you must do

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

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

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 FAVERIN.

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.

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 preventing unwanted side effects.

People taking FAVERIN may be more likely to think about killing themselves or actually try to do so, especially when FAVERIN is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using the medicine who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse during the first one to two months of taking FAVERIN until the medicine starts to work completely. This is more likely to occur if you are a young adult, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking FAVERIN, contact a doctor immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Things you must not do

Do not stop taking FAVERIN 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 FAVERIN 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 FAVERIN to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

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

Make sure you know how you react to FAVERIN before you drive or operate machinery.

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

If you drink large amounts of caffeine-containing beverages (eg. coffee, tea), minimise your intake of these beverages while taking FAVERIN. Taking large amounts of caffeine while taking the medicine may increase the amount of caffeine in your body, causing 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 FAVERIN. Families and carers should be aware of this. Special care may be needed.

After you have stopped taking FAVERIN, 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 FAVERIN.

Like other medicines, it 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.

Ask your doctor or pharmacist 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, muscle 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.

Other side effects observed more frequently in children are: abnormal thoughts or behaviour, cough, changes in menstruation, nose bleeds, increased restlessness, infection and sinusitis.

Contact your doctor immediately, or go to Accident & Emergency at your nearest hospital if any of the following occur: swelling of limbs, face, eyes, inside the nose, mouth or throat, shortness of breath, breathing or swallowing difficulties, thoughts of suicide or attempting suicide or self harm. These are very serious side effects and may indicate a serious allergic reaction. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

You may not experience any of them.

After using FAVERIN

Storage

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

If you take the tablets out of their container, they may not keep well.

Keep FAVERIN in a cool, dry place where it stays below 25°C. Do not store it, 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 this medicine 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 FAVERIN, or the tablets have passed their expiry date, ask your pharmacist what to do with any leftover tablets.

Product description

What it looks like

FAVERIN 50 mg tablets are white, round, biconvex tablets marked with "291" on one side, and with a line in the middle, making them easy to break in half if necessary. Packs of 10 or 30 tablets.

FAVERIN 100 mg tablets are white, oval shaped tablets marked with "313" on one side, and with a line through the middle, making them easy to break in half if necessary. Packs of 10 or 30 tablets.

Ingredients

Each FAVERIN Tablet contains 50 mg or 100 mg of the active ingredient fluvoxamine maleate. The tablet also contains mannitol, maize starch, pregelatinised potato starch, sodium stearyl fumarate, colloidal anhydrous silica, hypromellose, propylene glycol, talc and titanium dioxide.

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

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian Registration Numbers:

50 mg tablets: AUST R 90057

100 mg tablets: AUST R 64388

This leaflet was revised in October 2017