

Faverin[®]

50 mg and 100 mg film-coated tablets

fluvoxamine maleate

- **Faverin treats depression and Obsessive Compulsive Disorder (OCD).** Like all medicines it can have unwanted effects. It is therefore important that you and your doctor weigh up the benefits of treatment against the possible unwanted effects, before starting treatment.
- **Faverin should not be used to treat depression in children and adolescents under 18.** See section 2, Use in Children and adolescents under 18.
- **Faverin won't work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should see you regularly during your course of treatment. Tell your doctor if you haven't started feeling better.
- **Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, **see your doctor or go to a hospital straight away.**
- **Don't stop taking Faverin without talking to your doctor.** If you stop taking Faverin suddenly or miss a dose, you may get withdrawal effects. See Section 3, How to take Faverin.
- **If you feel restless and feel like you can't sit or stand still, tell your doctor.** Increasing the dose of Faverin may make these feelings worse.
- **Taking some other medicines with Faverin can cause problems.** You may need to talk to your doctor. See section 2, Are you taking any other medicines.
- **If you are pregnant or planning to get pregnant,** talk to your doctor. See section 2, Pregnancy and breastfeeding.

Read all of this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Faverin is and what it is used for**
- 2. Before you take Faverin**
- 3. How to take Faverin**
- 4. Possible side effects**
- 5. How to store Faverin**
- 6. Further information**

1. What Faverin is and what it is used for

Faverin belongs to a group of medicines called selective serotonin re-uptake inhibitors (SSRI). Faverin contains a substance called fluvoxamine. This is an antidepressant. It is used to treat depression (major depressive episode).

Faverin can also treat people who have obsessive compulsive disorder (OCD).

2. Before you take Faverin

Do not take Faverin if any of the following applies to you:

- You are allergic (hypersensitive) to fluvoxamine or any of the other tablet ingredients (see section 6 'Further information')
- You are taking medicines called monoamine oxidase inhibitors (MAOI) sometimes prescribed to treat depression or anxiety, including linezolid (an antibiotic which is also an MAOI).

Treatment with fluvoxamine should only be started at least 2 weeks after discontinuation of an irreversible MAOI. However treatment with fluvoxamine after discontinuation of certain reversible MAOIs can be started the following day. In exceptional cases linezolid (an antibiotic MAOI) may be used with fluvoxamine provided the doctor can monitor you closely. Your doctor will advise you how you should begin taking Faverin once you have stopped taking the MAOI.

- You are taking tizanidine, a medicine often used as a muscle relaxant.
- You are taking pimozide, a neuroleptic drug that is used for the treatment of schizophrenia and other psychiatric diseases.
- You are breast-feeding

If any of the above apply to you, **do not take** Faverin and talk to your doctor.

Warnings and precautions

Talk to your doctor or a pharmacist **before** taking your medicine if:

- you recently had a heart attack
- you are pregnant, or could be pregnant
- you have epilepsy
- you have a history of bleeding problems or if you regularly use medicines which increase the risk of bleeding, such as common pain killers, or if you are pregnant (see 'Pregnancy')
- you have diabetes
- you are having treatment with electroconvulsive therapy (ECT)
- you ever had mania (a feeling of elation or over-excitement)
- you have liver or kidney problems
- you have high pressure in your eyes (glaucoma)
- you are less than 18 years old (See also section 3 'How to take Faverin')
- you are taking medicinal products containing buprenorphine or buprenorphine/naloxone, as these products taken in combination with Faverin may lead to serotonin syndrome, a potentially life-threatening condition (for symptoms, see section 4, "Possible side effects") see also "Other medicines and Faverin".

If any of the above applies to you, your doctor will tell you whether it is safe for you to start taking Faverin.

Occasionally, **thoughts of restlessness** for example, you cannot sit or stand still (akathisia) may occur or may increase during the first few weeks of treatment with Faverin, until the antidepressant effect has worked.

Tell your doctor immediately if you experience these symptoms. Then a dosage adjustment may be helpful.

Severe skin reactions have been reported when using Faverin. **Stop taking Faverin** and contact a doctor immediately if you develop a rash or mucous membrane lesions. The severe rashes may include rash, starting on the extremities, usually on both sides of the body and evolving into concentric circles that resemble a target (erythema multiforme), widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis).

Medicines like Faverin (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet.

You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Tell your doctor immediately if you have any distressing thoughts or experiences.

Use in children and adolescents under 18 years of age

Children and adolescents under 18 years should not take this medicine, unless they are being treated for obsessive compulsive disorder (OCD).

This is because Faverin is not used to treat depression in people aged under 18 years.

When taking this type of medicine, people under 18 have an increased risk of side-effects such as attempting suicide, thoughts about suicide and hostility, such as aggression, oppositional behaviour and anger.

If your doctor has prescribed Faverin for someone under 18 years and you want to discuss this, please go back to your doctor. You should tell your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Faverin.

Also, it is not known whether taking Faverin under the age of 18 years can affect growth, maturation or development of intelligence or behaviour in the long term.

Other medicines and Faverin

- You should not start to take the herbal remedy St John's Wort while you are being treated with Faverin since this may result in an increase of undesirable effects. If you are already taking St John's Wort when you start on Faverin, stop taking the St John's Wort and tell your doctor at your next visit.
- If you have been taking a medicine to treat depression or anxiety within the last two weeks, or you suffer from schizophrenia, check with your doctor or a pharmacist.

Your doctor or pharmacist will check if you are taking other medicines to treat your depression or other related psychotic conditions, these may include:

- benzodiazepines
- tricyclic antidepressants
- neuroleptic or anti-psychotics
- lithium
- tryptophan
- Monoamine oxidase inhibitor (MAOI) such as moclobemide
- pimozone
- Selective serotonin reuptake inhibitor (SSRI) such as citalopram

Your doctor will tell you if it is safe for you to start taking Faverin.

You should also tell your doctor or pharmacist if you have been taking **any of the medicines listed** below:

- aspirin (acetylsalicylic acid) or aspirin-like medicines, used to treat pain and inflammation (arthritis)
- ciclosporin, used to reduce the activity of the immune system
- methadone, used to treat pain and withdrawal symptoms
- mexiletine, used to treat abnormal heart rhythms
- phenytoin or carbamazepine, used to treat epilepsy
- propranolol, used to treat high blood pressure and heart conditions
- ropinirole, for Parkinson's disease.
- a 'triptan', used to treat migraines, such as sumatriptan.
- terfenadine, used to treat allergies. Faverin should not be taken together with terfenadine.
- sildenafil, used to treat erectile dysfunction
- theophylline, used to treat asthma and bronchitis

- tramadol, a pain-killer
- buprenorphine or buprenorphine/naloxone
- clopidogrel, warfarin, nicoumalone or any other drug used to prevent blood clots

If you are taking or have recently taken any of the medicines in the above list and you have not already discussed these with your doctor, go back to your doctor and ask what you should do. Your dose may need to be changed or you may need to be given a different medicine.

Please tell your doctor or pharmacist if you are taking or have taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Taking Faverin with food and drink

- Do not drink alcohol if you are taking this medicine. This is because alcohol works together with Faverin and will make you sleepy and unsteady.
- If you normally drink a lot of tea, coffee and soft drinks with caffeine in them, you may have symptoms such as your hands shaking, feeling sick, fast heart rate (palpitations), restlessness and difficulty sleeping (insomnia). If you lower how much caffeine you drink, these symptoms might disappear.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

There is only limited experience concerning the use of fluvoxamine during pregnancy. **Do not take fluvoxamine if you are pregnant, unless your doctor considers it absolutely necessary. If you are currently taking fluvoxamine and are planning to become pregnant or to father a child, please consult with your physician to decide if an alternative medication is necessary or appropriate**

If you take fluvoxamine near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking fluvoxamine so they can advise you.

Fluvoxamine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Make sure your midwife and/or doctor know you are on fluvoxamine. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like fluvoxamine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

You should not discontinue treatment with fluvoxamine abruptly. If you are taking fluvoxamine in the last 3 months of pregnancy, your baby might have some other symptoms when it is born in

addition to having trouble breathing or bluish skin, such as not being able to sleep or feed properly, being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, drowsiness, tremors, jitters or fits. If your baby has any of these symptoms when it is born contact your doctor immediately.

Breast-feeding

Fluvoxamine passes into breast milk. There is a risk of an effect on the baby. Therefore, you should discuss the matter with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with fluvoxamine.

Driving and using machines

You can drive and use machines while you are taking this treatment, so long as this medicine does not make you sleepy.

Faverin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Faverin

How much Faverin to take

Always take Faverin as your doctor has told you to.

You should check with your doctor or pharmacist if you are not sure.

Usual starting dose for adults (18 years and older):

The treatment for depression:

- Start with 50 or 100 mg daily, taken in the evening.

The treatment for obsessive compulsive disorder:

- Start with 50mg daily, preferably in the evening.

If you don't start to feel better after a couple of weeks, talk to your doctor, who will advise you. He or she may decide to increase the dose gradually.

The highest daily dose that is recommended is 300 mg.

If your doctor advises you to take more than 150 mg per day, **do not take** them all at once; ask your doctor when you should take them.

The usual dose for children and adolescents with obsessive compulsive disorder - OCD (8 years and older is):

Start with 25mg (half a tablet) per day, preferably at bedtime. Your doctor may increase the dose every 4 – 7 days in 25 mg increments as tolerated until an effective dose is achieved.

The highest daily dose is 200mg.

If your doctor advises you to take more than 50 mg per day, **do not take** them all at once; ask your doctor when you should take them. If the dose is not divided equally, the larger dose should be taken at night.

Children and adolescents under the age of 18 **should not take** this medicine to treat depression. This medicine should be prescribed for children or adolescents for Obsessive Compulsive Disorder (OCD) **only**.

How to take Faverin

- Swallow the tablets with water. **Do not** chew them.

You can break the tablets in half if your doctor has advised you to

How long does it take to work?

Faverin may take a little time to start working. Some patients do not feel better in the first 2 or 3 weeks of treatment.

Keep taking your tablets until your doctor tells you to stop. Even when you start feeling better, your doctor may want you to carry on taking the tablets for some time, for at least six months to make sure that the medication has worked completely.

Do not stop taking Faverin too quickly.

You may suffer from **withdrawal symptoms** such as:

- agitation and anxiety
- confusion
- diarrhoea
- difficulty sleeping/ intense dreams
- dizziness
- emotional instability
- headaches
- irritability
- nausea and/or vomiting
- palpitation (faster heartbeats)
- sensory disturbance (such as electric shock sensations or visual disturbances)
- sweating
- tremors

When stopping Faverin your doctor will help you to reduce your dose slowly over a number of weeks or months, this should help reduce the chance of withdrawal effects. Most people find that any symptoms on stopping Faverin are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer.

If you get withdrawal effects when you are coming off your tablets your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking Faverin, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly (see section 4 'Possible Side Effects').

If you experience any symptoms on stopping the treatment, **contact** your doctor.

If you take more Faverin than you should

If you or someone else takes too much Faverin (an overdose), talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

Symptoms of overdose include, but are not limited to, nausea, vomiting, diarrhoea and feeling drowsy or dizzy. Cardiac events (slow or fast heartbeat, low blood pressure), liver problems, convulsions (fits) and coma have also been reported.

If you forget to take Faverin

If you miss a tablet, wait until the next dose is due. Do not try to make up for the dose you have missed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Faverin can cause side effects (unwanted effects or reactions), but not everyone gets them.

Frequencies of the observed side effects are defined as:

very common	affects more than 1 user in 10
common	affects 1 to 10 users in 100
uncommon	affects 1 to 10 users in 1,000
rare	affects 1 to 10 users in 10,000
very rare	affects less than 1 user in 10,000
not known	frequency cannot be estimated from the available data

Side effects related to this type of medicine

Occasionally, **thoughts of suicide or self harm** may occur or may increase in the first few weeks of treatment with Faverin, until the antidepressant effect has worked.

Tell your doctor immediately if you have any distressing thoughts or experiences.

If you **have several symptoms at the same time** you might have one of the following rare conditions:

- Serotonin syndrome: if you have sweating, muscle stiffness or spasms, instability, confusion, irritability or extreme agitation.
- Neuroleptic malignant syndrome: if you have stiff muscles, high temperature, confusion and other related symptoms.
- SIADH: if you feel tired, weak or confused and have achy, stiff or uncontrolled muscles.

- Severe skin reactions like severe skin rashes or redness, including rash, starting on the extremities, usually on both sides of the body and evolving into concentric circles that resemble a target (erythema multiforme), widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis). The frequency of these side effects is not known (cannot be estimated from the available data).

Stop taking Faverin and **contact your doctor immediately**.

If unusual bruising or purple patches appear on your skin or you vomit blood or pass blood in your stool, contact your doctor for advice.

Stopping of fluvoxamine (particularly when abrupt) commonly leads to withdrawal symptoms (see section 3 withdrawal symptoms).

Sometimes patients **feel slightly sick** as Faverin begins to work. Although the feeling of sickness is unpleasant, it should soon pass if you keep taking your tablets as prescribed. This may take a few weeks.

Side effects specifically related to Faverin

Common side effects:

- agitation
- anxiety
- constipation
- diarrhoea
- difficulty sleeping
- dizziness
- dry mouth
- faster heart beat
- feeling drowsy (lethargy)
- feeling unwell (malaise)
- headache
- indigestion
- loss of appetite
- nervousness
- stomach pain
- sweating
- tremor
- muscle weakness (asthenia)
- vomiting

Uncommon side effects:

- allergic skin reactions (including swelling of face, lip or tongue, rash or itching)
- confusion

- delayed ejaculation
- dizziness when standing up too quickly
- hallucinations
- lack of co-ordination
- muscle or joint pain
- aggression

Rare side effects:

- convulsions
- liver complaints
- mania (a feeling of elation or over-excitement)
- sensitivity to sunlight
- unexpected milk flow

Other side effects reported (frequency not known):

- akathisia (restlessness)
- abnormal taste
- anorgasm (failure to achieve orgasm)
- for female patients: disorders with menstruation (monthly bleeding)
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information.
- micturition disorders (such as the need to urinate frequently during the day and/or the night, the sudden lack of control over urination during the day and/or the night, or the lack of ability to urinate)
- paraesthesia (tingling or numbness)
- glaucoma (increased pressure in eye)
- dilated pupils
- increase in the hormone prolactin (a hormone that supports milk production in a nursing mother)
- weight changes

An increased risk of bone fractures has been observed in patients taking this type of medicine.

Side effects related to the treatment for OCD, in children and adolescents, no frequencies are given:

- Hypomania (a feeling of elation and over excitement)
- Agitation
- Convulsions
- Difficulty sleeping (insomnia)
- Lack of energy (asthenia)
- Hyperactivity (hyperkinesia)
- Feeling Drowsy (somnolence)
- Indigestion

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

In Ireland:

HPRA Pharmacovigilance

Website: www.hpra.ie

In Malta:

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Faverin

- **Keep out of the reach and sight of children.**
- Do not use the tablets after the expiry date (EXP) which is printed on the carton and blister pack.
- Do not store above 25°C.

If your doctor stops your treatment, return any unused tablets to a pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Faverin 50 mg /100mg contains

The active substance is fluvoxamine maleate. Each 50mg tablet contains 50 mg of fluvoxamine maleate. Each 100mg tablet contains 100 mg of fluvoxamine maleate.

The other ingredients are: mannitol (E421), maize starch, pregelatinized starch, sodium stearyl fumarate, colloidal anhydrous silica, hypromellose, macrogol 6000, talc and titanium dioxide (E171).

What Faverin looks like and contents of the pack

The Faverin 50 mg tablet is film-coated, white to off-white, round and marked "291" on both sides of the score line.

The Faverin 100 mg tablet is film-coated, white to off-white, oval and marked "313" on both sides of the score line.

Faverin 50mg is available in packs of 5, 10, 20, 30, 50, 60, 90, 100 and 250 tablets.

Faverin 100mg is available in packs of 15, 20, 30, 50, 60, 90, 100, 120 or 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is
Viartis Healthcare Limited,
Damastown Industrial Park,
Mulhuddart Dublin 15,
DUBLIN Ireland

Faverin is made by Mylan Laboratories SAS, Route de Belleville, Lieu dit Maillard, 01400
Châtillon-sur- Chalaronne, France.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Floxyfral
Belgium	Floxyfral
France	Floxyfral
Germany	Fevarin
Greece	Dumyrox
Ireland	Faverin
Italy	Dumirox
Luxembourg	Floxyfral
Norway	Fevarin
Portugal	Dumyrox
Spain	Dumirox
Sweden	Fevarin
The Netherlands	Fevarin
United Kingdom (NI)	Faverin

This leaflet was last revised in June 2024