

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Favoxil 50 mg Tablets

Each Favoxil 50 tablet contains 50 mg Fluvoxamine maleate

Favoxil 100 mg Tablets

Each Favoxil 100 tablet contains 100 mg Fluvoxamine maleate

Inactive ingredients and allergens in the medicine see in section 6 "**Additional information**".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

Favoxil is not intended for the treatment of depression in children and adolescents under the age of 18. See in section 2 "**Children and adolescents**".

The effect of Favoxil is not immediate. Some of the patients taking antidepressants may feel worse before feeling better. You should visit the doctor regularly and consult him if your feeling has not improved.

Some people who are depressed or anxious think of suicide or self-harm. If you start feeling bad or think of suicide or harming yourself, **refer to your doctor or to a hospital immediately. Do not stop treatment with Favoxil without consulting the doctor.** If you suddenly stop the use of the medicine or miss a dose, you may experience withdrawal symptoms (see section 3 "**How should you use the medicine?**").

If you feel restless or you cannot sit or stand still, tell the doctor. Increasing the dose of Favoxil may make these feelings worse.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in children, adolescents and young adults up to 25 years of age.

At the beginning of the treatment with the medicine, patients of all ages and their relatives should follow behavioral changes such as: worsening of depression, suicidal thoughts, aggressiveness, etc. In case changes like these occur, refer to the doctor immediately.

1. What is the medicine intended for?

For the treatment of emotional disorders characterized by prolonged low moods, psychomotor disorders and psychosomatic complaints, including symptoms of depression. Favoxil is also used to treat patients suffering from obsessive compulsive disorder (OCD).

Therapeutic group:

Antidepressants, selective serotonin reuptake inhibitors (SSRIs).

2. Before using the medicine

Do not use the medicine if:

- You are (hypersensitive) allergic to the active ingredient fluvoxamine or to any of the additional ingredients the medicine contains (see section 6 "**Additional information**").
- You are taking medicines from the monoamine oxidase inhibitors (MAOIs) group sometimes prescribed to treat depression or anxiety, including linezolid (an antibiotic which is also a MAOI). Treatment with Favoxil should be started at least two weeks after stopping treatment with a medicine of the irreversible monoamine oxidase inhibitors group (irreversible MAOIs). However treatment with Favoxil can be started the day after stopping treatment with certain reversible monoamine oxidase inhibitors (reversible MAOIs). In exceptional cases linezolid (an antibiotic which is also a MAOI) can be used concomitantly with Favoxil provided the doctor can monitor you closely. Refer to the doctor for medical consultation on how to begin taking Favoxil after stopping treatment with the MAOI.
- You are taking tizanidine. This medicine is usually 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 breastfeeding.

If any of the above applies to you, **do not take Favoxil.** Talk to your doctor about it.

Special warnings regarding the use of this medicine

Before treatment with Favoxil, tell the doctor if:

- you have 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 take medicines that may increase the risk of bleeding, such as common pain relievers.
- you have diabetes.
- you are being treated with electroconvulsive therapy (ECT).
- you have ever experienced mania (a feeling of elation or over-excitement).
- you have liver or kidney problems.
- you have high intraocular pressure (glaucoma).
- you are under 18 years of age (See section 3 "**How should you use the medicine?**").

If any of the warnings above applies to you, your doctor will decide whether it is safe for you to use Favoxil.

Occasionally, **feelings of restlessness**, such as inability to sit or stand still (akathisia) may occur or may increase during the first few weeks of treatment with Favoxil, until the antidepressant effect begins. Tell the doctor immediately if you experience these symptoms. It may be needed to adjust the dosage.

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

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

Suicidal thoughts and worsening of the depression or anxiety:

In states of depression and/or anxiety, you may think of hurting yourself or even of suicide. These thoughts may increase at the beginning of treatment with antidepressants, since these medicines take time to take effect, usually after two weeks of treatment, and sometimes longer. The likelihood of these thoughts increases if:

- you have previously had suicidal thoughts or thoughts on self-harm.
- you are a young adult. Clinical studies have shown an increased risk of suicidal behavior in adults aged less than 25 years who were treated with antidepressants for psychiatric conditions.

If you have thoughts of harming yourself or of committing suicide at any time, **refer to a doctor or to a hospital emergency room immediately.**

It is recommended that you share your condition with a relative or close friend, if you are suffering from depression or anxiety. Ask them to read this leaflet. It is recommended you ask them to alert you if they think your depression or anxiety is getting worse, or if there are changes in your behavior. If you have distressing thoughts or experiences, **refer to the doctor immediately.**

Children and adolescents
Use in children and adolescents under the age of 18 years:
Favoxil is not intended for treatment of children and adolescents under the age of 18, unless the medicine is being used to treat of obsessive compulsive disorder (OCD), since Favoxil is not used to treat depression in patients under the age of 18.

In children and adolescents under the age of 18 who are taking this medicine, there is an increased risk of side effects such as attempting suicide, suicidal thoughts and hostility such as aggression, oppositional behavior and anger.

If the doctor prescribed Favoxil for someone under the age of 18, and you would like to discuss it with the doctor, refer to them again. You should report to the doctor if any of the listed side effects develop or worsen when the patient is under the age of 18 and taking Favoxil.

Additionally, it is not known whether taking Favoxil under the age of 18 can affect growth, maturation, cognitive and behavioral development in the long term.

Drug interactions

• If you are taking, or have recently taken other medicines, including non-prescription drugs, nutritional supplements and medicinal herbs, tell the doctor or pharmacist, especially if you are taking Hypericum (St. John's wort). Do not start treatment with the herbal remedy Hypericum (St. John's wort) during treatment with Favoxil, as the frequency of side effects may rise. If you are taking Hypericum (St. John's wort) before commencing treatment with Favoxil, stop use of Hypericum (St. John's wort) and tell the doctor about it.

• 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 pharmacist.

Your doctor or pharmacist will check if you are taking other medicines, for treatment of depression or similar conditions, which may include:

- benzodiazepines.
- tricyclic antidepressants.
- neuroleptics or anti-psychotics.
- lithium.
- tryptophan.
- medicines of the monoamine oxidase inhibitors (MAOIs) group such as moclobemide.
- pimozide
- selective serotonin reuptake inhibitors (SSRIs) such as citalopran.

Your doctor will decide whether it is safe for you to start taking Favoxil.

You should also tell your doctor or pharmacist if are taking any of the medicines listed below:

- aspirin (acetylsalicylic acid) or aspirin-like medicines to treat pain and inflammation (arthritis).
- ciclosporin to reduce the activity of the immune system.
- methadone to treat pain and withdrawal symptoms.
- mexiletine, used to treat abnormal heart rhythms
- phenytoin or carbamazepine to treat epilepsy.
- propranolol to treat high blood pressure and heart conditions.
- ropinirole to treat Parkinson's disease.
- medicines of the triptan group to treat migraine, e.g., sumatriptan
- terfenadine to treat allergies. Do not take Favoxil together with terfenadine.
- sildenafil to treat erectile dysfunction.
- theophylline to treat asthma and bronchitis.
- tramadol to relieve pain.
- clopidogrel, warfarin, nicoumalone or any other medicine used to prevent blood clots.

If you are using or have recently used any of the medicines listed above and did not report it to your doctor, you should return to the doctor and update him so that he can instruct on how to continue. He may change your dose or switch the medicine.

Use of the medicine and food

If you consume a lot of drinks containing caffeine (e.g., tea, coffee and certain soft drinks) during the treatment, you may suffer from symptoms such as: shaking hands, nausea, increased heart rate (palpitations), restlessness, insomnia. These symptoms may disappear if you lower how much caffeine you drink.

Use of this medicine and alcohol consumption

Abstain from drinking alcoholic beverages during the treatment with Favoxil. Alcohol together with Favoxil causes sleepiness and unsteadiness.

Pregnancy, breastfeeding and fertility

Consult your doctor or pharmacist before taking any medicine.

Pregnancy

Experience regarding the use of Favoxil during pregnancy is limited. **Do not use Favoxil if you are pregnant, unless your doctor has instructed you otherwise and has decided that the treatment is necessary. If you are taking Favoxil and are planning a pregnancy, or if you are now taking Favoxil and planning to father a child, consult the doctor who will decide if there is a need for an appropriate alternative medicine.**

If you take Favoxil near the end of your pregnancy there is 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 the medicine so they can advise you.

Animal studies have shown that Favoxil impairs the quality of sperm. Theoretically, an impact on fertility in humans is possible but it has not been observed yet.

Inform the midwife and/or doctor you are taking Favoxil. If you take Favoxil during pregnancy, particularly in the last 3 months of pregnancy, medicines like Favoxil may increase the risk of

a serious condition in babies called persistent pulmonary hypertension of the newborn (PPHN), which causes rapid breathing and a bluish appearance. These symptoms usually begin within the first 24 hours following delivery. If you notice these effects, refer to the midwife or doctor immediately.

Do not stop treatment with Favoxil abruptly. If you have taken Favoxil in the last 3 months of pregnancy, the baby may experience additional symptoms besides breathing problems or bluish skin, such as: difficulty sleeping or feeding properly, the baby may be too hot or too cold, being sick, cry a lot, suffer from muscle weakness or muscle stiffness, lethargy, drowsiness, tremor, jitters or fits. If you notice these symptoms in your baby, refer to a doctor immediately.

Breastfeeding

Do not breastfeed. Favoxil passes into breast milk. There is a risk of an effect on the baby and therefore you should consult your doctor who will decide whether you should stop breastfeeding or stop the treatment with Favoxil.

Driving and use of machinery

You can drive or operate dangerous machinery while using the medicine, as long as the medicine does not make you sleepy.

Important information about the ingredients of the medicine

This medicine contains less than 23 mg sodium per tablet, and is therefore considered "sodium-free".

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only. Usual recommended dosage is:

Starting dose in adults aged 18 and older
To treat depression: start with 50 mg or 100 mg daily, taken in the evening.

To treat obsessive compulsive disorder (OCD): start with 50 mg daily, preferably in the evening.

If you do not feel an improvement to your condition after a couple of weeks, you should consult your doctor. He may decide to increase your dose gradually.

The highest recommended daily dose is 300 mg. If your doctor advises you to take more than 150 mg per day, **do not take the whole dose at once.** Ask the doctor when and how to take it.

Usual dose in children and adolescents with obsessive compulsive disorder (OCD) aged 8 and older:

Starting dose of 25 mg (half of a 50 mg tablet) daily, preferably taken before bedtime. The doctor may increase the dose every 4-7 days in 25 mg increments based on your response until the effective dose is achieved.

The highest daily dose is 200 mg. If your doctor advises you to take more than 50 mg per day, **do not take the whole dose at once.** Ask the doctor when and how to take it. If the dose cannot be divided equally, take the higher dose at night.

Do not exceed the recommended dose.

Use of the medicine to treat depression is **not intended** for children and adolescents under the age of 18. The medicine should be prescribed for children or adolescents for Obsessive Compulsive Disorder (OCD) **only.**

Duration of treatment:

Favoxil takes a little time to start taking effect. Some patients do not feel an improvement to their condition in the first 2-3 weeks of treatment. If you do not start feeling an improvement after a couple of weeks, consult with your doctor, who may gradually increase your dose.

Keep taking your tablets until your doctor asks you to stop. Even if you start feeling better, your doctor may instruct you to carry on taking the tablets for at least 6 months to make sure that the treatment has worked completely.

The dosage can be taken once a day, preferably in the evening, or by dividing it to a number of times throughout the day, as per the doctor's decision.

Method of administration:

Swallow the medicine with water. There is no information regarding chewing and crushing. The tablet can be halved as per the doctor's instruction.

If you accidentally took a higher dose: symptoms of an overdose can include, among others nausea, vomiting, diarrhea, feeling drowsy or dizzy. There have also been reports of cardiac events (slow or fast heart rate, low blood pressure), liver problems, fits and coma. If you

have taken an overdose or if a child or anyone else has accidentally swallowed the medicine, refer to the doctor or to a hospital emergency room immediately and bring the package of the medicine with you.

If you forget to take this medicine at the set time, do not take a double dose to compensate for a forgotten one. Take the next dose at the usual set time and consult the doctor.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop the treatment with this medicine abruptly without consulting the doctor.

Do not stop taking the medicine too quickly, as you can suffer from **withdrawal symptoms** such as: agitation; anxiety; confusion; diarrhea; insomnia/intense dreams; dizziness; emotional instability; headaches; irritability; nausea and/or vomiting; palpitations (rapid heartbeat); sensory disturbances (like sensation of electric shock or visual disturbances); sweating; tremor. Before stopping treatment with Favoxil, discuss the ramifications with the doctor.

When stopping treatment with Favoxil, the doctor will instruct you how to slowly and gradually lower the dosage over a number of weeks or months, so that the risk of withdrawal effects from the medicine will be reduced.

If you suffer from withdrawal symptoms from the medicine, refer to the doctor, he may decide to lower the dosage more slowly.

These symptoms are usually mild and pass within approximately two weeks, but in some patients, these effects may be more severe or persist for a longer period.

If you experience withdrawal symptoms during the dosage reduction, your doctor may decide that you should reduce the dosage more slowly. If you experience severe withdrawal effects when discontinuing the medicine refer to the doctor. The doctor may ask you to start using the medicine again and instruct you to stop the use much more slowly (see section 4 "**Side effects**"). If you experience any symptoms when stopping the treatment, **refer to your doctor.**

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Favoxil may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Side effects related to the therapeutic group: Occasionally, **thoughts of self-harm or suicide** may occur or increase during the first weeks of treatment until the antidepressants effect of Favoxil begins.

If you experience such thoughts or have disturbing experiences, **refer to the doctor immediately.**

If you **suffer from a number of side effects simultaneously,** you may have one of the following rare conditions:

- Serotonin syndrome: if you suffer from sweating, muscle stiffness or spasms, instability, confusion, irritability or extreme emotional turmoil.
- Neuroleptic malignant syndrome: if you suffer from muscles stiffness, high fever, confusion and additional related symptoms.
- Syndrome of inappropriate antidiuretic hormone secretion (SIADH): if you feel tired, weak or confused and suffer from achy, stiff or uncontrollable muscles.
- Severe skin reactions, such as severe skin rash or redness, including a rash starting on the arms and legs, usually on both sides of the body, that evolve into centric circles that resemble a target (erythema multiforme), widespread rash with blisters and peeling skin, particularly in the area of 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 unknown (cannot be determined from the existing data).

Stop using Favoxil and refer to the doctor immediately.

If unusual bruising or purple patches appear on your skin or you have bloody vomit or bloody stools, refer to the doctor.

Discontinuing treatment with Favoxil (particularly when done abruptly) usually leads to withdrawal symptoms (see section 3 "**How should you use the medicine?**").

You may **feel slightly sick** when Favoxil begins to take effect. Even though this ill feeling is unpleasant, it should soon pass, sometimes within a few weeks if you adhere to your treatment.

Side effects related to Favoxil:
Common side effects (appear in 1-10 users out of 100):

Agitation; anxiety; constipation; diarrhea; difficulty sleeping; dizziness; dry mouth; rapid heartbeat; drowsiness (lethargy); feeling generally unwell (malaise); headache; indigestion; lack of appetite; nervousness; abdominal pain; sweating; tremor; muscle weakness (asthenia); vomiting.

Uncommon side effects (appear in 1-10 users out of 1,000):

Allergic skin reactions (including swelling of the face, lips or tongue, rash or itching); confusion; delayed ejaculation; dizziness when standing up too quickly; hallucinations; lack of coordination; muscle or joint pain; aggression.

Rare side effects (occur in 1-10 users in 10,000):

Convulsions; liver problems; mania (feeling of elation or over-excitement); sensitivity to sunlight; unexpected milk flow.

Additional side effects:

Restlessness (akathisia); disturbed sense of taste; inability to achieve an orgasm; menstrual cycle disorders in women; heavy vaginal bleeding shortly after birth (see "**pregnancy**" in section 2 for more information); micturition disorders (such as a need to urinate more frequently during the day and/or night, sudden lack of control over urination during the day and/or night or inability to urinate); paresthesia (tingling or numbness); increased intraocular pressure (glaucoma); dilated pupils; increase in the prolactin hormone (a hormone responsible for milk production in breastfeeding women); weight changes; an increased risk of fractures has been observed among patients taking this type of medicine.

Side effects related to the treatment for Obsessive Compulsive Disorder, in children and adolescents, (frequencies have not been reported):

Hypomania (a feeling of elation and over excitement); agitation; convulsions; difficulty sleeping (insomnia); lack of energy (asthenia); hyperactivity (hyperkinesia); feeling drowsy (somnolence); indigestion.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects from Drug Treatment" that can be found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

Additionally, you can report to Padagis via the following address: Padagis.co.il

5. How to Store the Medicine?

Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor. Do not use the medicine after the expiry date (exp. date) that appears on the carton and blister pack. The expiry date refers to the last day of that month.

Store below 25°C. If your doctor decides to stop the treatment, return any remaining tablets to a pharmacist. Do not dispose of them via wastewater or household waste. These measures will help to protect the environment.

6. Additional information

• In addition to the active ingredient, the medicine also contains:

Mannitol, maize starch, eudragit L-30-D, pregelatinized starch, talc, sodium stearyl fumarate, glyceryl triacetate, colloidal anhydrous silicon, titanium dioxide, povidone, yellow iron oxide.

• What the medicine looks like and contents of the package:
The 50 mg tablet is a round, yellow colored tablet. A score line on one side and "AGIS" embossed on the other side. Quantity in package: 10, 20 or 60 tablets packed in blisters (each blister contains 10 tablets). The 100 mg tablet is an elongated, yellow colored tablet. A score line on one side. Quantity in package: 10, 30 or 60 tablets packed in blisters (each blister contains 10 tablets).

• Not all package sizes may be marketed.
• **Registration holder and address:** Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.
• Revised in August 2022 according to MOH guidelines.
• Drug registration number at the national medicines registry of the Ministry of Health: Favoxil 50 mg: 4192.25727 Favoxil 100 mg: 4191.25728

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