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

The medicine is dispensed with a doctor's prescription only

Prizma Solution

Composition:

Each 5 ml of **Prizma Solution** contains:

Fluoxetine (as HCl) 20 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Antidepressants and anti-anxiety medicines increase the risk for suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25.
When starting treatment with the medicine, patients of all ages, and their relatives, must monitor for behavioral changes, such as worsened depression, suicidal thoughts, aggressiveness and the like.
If such changes occur, refer to a doctor immediately.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat:

Adults:

- major depressive episodes.
- obsessive compulsive disorder (OCD).
- bulimia nervosa: Fluoxetine is given as an add-on treatment to psychotherapy to reduce uncontrolled eating binge episodes and purging disorder.

Children and adolescents aged 8 years and above:

- Moderate to severe major depressive disorder, if the depression does not respond to psychological therapy after 4-6 sessions. Antidepressants should be offered to a child or young person with moderate to severe depression **only** in combination with psychological therapy.

Therapeutic group: Prizma Solution 20 mg/5 ml contains the active substance fluoxetine and belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs).

How does the medicine work?

Everyone has the substance called serotonin in their brain. People who suffer from depression or obsessive-compulsive disorder have a lower level of serotonin than people who do not suffer from these conditions. The exact mechanism of action of **Prizma Solution** and SSRI inhibitors is not fully understood, but they help increase the levels of serotonin in the brain. Treating these conditions will make you feel better. If these conditions are not treated, your condition will not change and may even get worse and be more difficult to treat. The treatment should last for several weeks or months to ensure that you do not suffer from the symptoms.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to fluoxetine or to any of the additional ingredients contained in the medicine (see section 6 "Further information"). If you develop a rash or other allergic reactions (such as itching, swollen lips or face or shortness of breath), stop taking the medicine straight away and contact your doctor immediately.
- You are taking medicines from the irreversible non-selective monoamine oxidase inhibitors class (MAOIs) – use of these medicines together with **Prizma Solution** can lead to life-threatening reactions for you (medicines to treat depression such as nialamide, iproniazide, modobemide, phenelzine, tranylcypromine, isocarboxazid, toloxatone, and linezolid (an antibiotic)).
  Wait at least 14 days after discontinuation of treatment with irreversible, non-selective MAOIs before starting treatment with this medicine.
  Do not start treatment with irreversible, non-selective monoamine oxidase inhibitor (MAOIs) types of antidepressants, if at least 5 weeks have not elapsed since the discontinuation of use of **Prizma Solution**. If you have been taking **Prizma Solution** for a long time or you have been taking a particularly high dose, your doctor will consider whether to wait longer than 5 weeks before starting treatment with MAOIs.
  However, fluoxetine therapy can be started one day after the end of treatment with certain reversible MAOIs, such as linezolid, moclobemide, methylthioninium (methylene blue).
- You are taking metoprolol (to treat heart failure) – taking it together with **Prizma Solution** increases the risk of slowing of the heart rate.

Special warnings regarding use of the medicine

Before beginning treatment or during treatment with Prizma Solution, tell the doctor if:

- you suffer from heart problems.
- you suffer from appearance of fever, muscle stiffness or tremor, changes in your mental state such as confusion, irritability, agitation; you may be suffering from a condition called "serotonin syndrome" or "neuroleptic malignant syndrome". This syndrome is very rare, but it may result in life-threatening conditions. **Contact your doctor immediately**; it may be necessary to stop treatment with the medicine.
- you suffer from or have previously suffered from mania/hypomania; if you experience a manic episode, contact your doctor immediately; it may be necessary to stop treatment with the medicine.
- you have previously suffered from bleeding, bruising or unusual bleeding, which may be affected by a medicine, or if you are pregnant.
- you are being treated with medicines that thin the blood (see subsection "Drug interactions" in this section).
- you suffer from epilepsy or seizures. If you experience seizures or there is an increase in seizure frequency, contact your doctor immediately; it may be necessary to stop treatment with the medicine.
- you are undergoing electro-convulsive therapy (ECT).
- you are undergoing treatment with tamoxifen (a medicine to treat breast cancer) (see subsection "Drug interactions" in this section).
- you suffer from a feeling of restlessness, and an inability to sit or stand still (akathisia). Increasing your dose of **Prizma Solution** may make these symptoms worse.
- you suffer from diabetes (your doctor may need to adjust your dose of antidiabetics, as **Prizma Solution** contains sucrose).
- you suffer from liver or kidney problems. A lower dose of **Prizma Solution** may be suitable for you. Your doctor may need to adjust the dosage of medicines to treat the liver.
- you suffer from a low resting heart rate and/or if you know that you may have salt depletion as a result of prolonged diarrhea and vomiting or as a result of usage of diuretics.
- you are being treated with diuretics, especially if you are elderly.
- you suffer from glaucoma (increased pressure in the eye).
- you are taking medicines from the irreversible non-selective monoamine oxidase inhibitor(MAOIs) family.
- you suffer from alcoholism. You must not consume alcohol while you are taking **Prizma Solution**.
- you suffer from a rare inherited syndrome in which you suffer from fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- you suffer from side effects as a result of drug interactions (see subsection "Drug interactions" in this section).

Medicines like **Prizma Solution** (from the SSRI/SNRI group) may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.

Thoughts of suicide and worsening of your depression

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming yourself. This condition may worsen when first starting treatment with antidepressants, since these medicines begin to have an effect after about two weeks or more from treatment initiation.

Suicidal thoughts are more common if:

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

If thoughts of killing or harming yourself occur, contact your doctor or go to a hospital straight away.

It is advisable to tell a relative or close friend that you are depressed or experience anxiety disorders, and ask them to read this leaflet. Ask them to tell you if they noticed your depression or anxiety disorder is getting worse, or if they are worried about changes in your behavior.

Children and adolescents

Patients under 18 years of age are at higher risk of suffering from side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behavior and anger) when taking this type of medicine. **Prizma Solution** should only be used in children and adolescents 8 to 18 years of age for the treatment of moderate to severe major depressive episodes (in combination with psychological therapy) and the medicine should not be used to treat other conditions.

Additionally, only limited information concerning the long-term safety of **Prizma Solution** on growth, puberty, and mental, emotional and behavioral development in this age group is available. Despite this, if you are under the age of 18, your doctor may prescribe **Prizma Solution** for you to treat moderate to severe major depressive episodes, in combination with psychological therapy, because he/she decided that it is in your best interest. If you are under the age of 18 and your doctor prescribed **Prizma Solution** for you and you want to discuss it, please return to your doctor. If you are under the age of 18, inform your doctor if one of the symptoms listed above develops or worsens while taking **Prizma Solution**.

Do not use **Prizma Solution** in children under the age of 8.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist:

Do not take **Prizma Solution** with:

- Irreversible, non-selective monoamine oxidase inhibitors (MAOIs), some used to treat depression. Irreversible, non-selective MAOIs must not be used together with **Prizma Solution** due to concern of a serious or even fatal reaction ("serotonin syndrome") that can occur (see subsection "Do not use the medicine if" in this section). Treatment with **Prizma Solution** should be started at least two weeks after you stop taking a medicine from the irreversible, non-selective MAOI family (such as tranylcypromine). Wait at least 5 weeks after you stop taking **Prizma Solution** before starting treatment with irreversible, non-selective MAOIs (see subsection "Do not use the medicine if" in this section). Your doctor will consider whether to wait longer than 5 weeks before starting treatment with MAOIs if you have been taking **Prizma Solution** for a long time or if the dose you have used has been high. Several medicines from the MAOI A group (e.g., moclobemide, linezolid, methylthioninium chloride (methylene blue) type B and selegiline) can be taken while using **Prizma Solution** provided your doctor will check you more often.
- Metoprolol to treat heart failure; taking together with **Prizma Solution** increases the risk of your heart rate becoming too slow.

Prizma Solution may affect the way the following medicines work:

- Tamoxifen (a medicine to treat breast cancer); **Prizma Solution** may change the blood levels of this medicine, thus reducing its effectiveness. Your doctor will consider prescribing a different antidepressant treatment.
- Alcohol.
- Monoamine oxidase inhibitors A (MAOI-A) including moclobemide, linezolid (an antibiotic) and methylthioninium chloride (also called methylene blue, used for the treatment of methemoglobinemia), due to the risk of life-threatening reactions occurring (serotonin syndrome). Treatment with fluoxetine can be started the day after stopping treatment with reversible MAOIs, but the doctor may wish to monitor you and will instruct you to use a lower dose of MAOI-A medicines.
- Mequitazine (a medicine for treatment of allergy); taking this medicine together with **Prizma Solution** may increase the risk of changes in the electrical activity of the heart.
- Phenytoin (for treatment of epilepsy); **Prizma Solution** may alter the blood level of this medicine. Your doctor may start treatment with phenytoin very carefully and consider closely monitoring your condition.
- Medicines that increase level of serotonin such as: lithium, selegiline, preparations containing the Hypericum herb (St. John's Wort), tramadol (a painkiller), medicines containing triptans (for treatment of migraine), medicines containing tryptophan; these medicines, when combined with **Prizma Solution**, can cause an increase in the incidence of serotonin syndrome. Your doctor may perform check-ups that are more frequent.
- medicines that may affect the heart's rhythm, e.g., Class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, antimicrobial medicines (e.g., sparfloxacin, moxifloxacin, erythromycin IV, pentamidine), medicines to treat malaria, particularly halofantrine, or antihistamines (astemizole, mizolastine). Taking these medicines together with **Prizma Solution** may increase the risk of changes in the electrical activity of the heart.
- Anti-coagulants (such as warfarin), NSAIDs (such as ibuprofen, diclofenac), aspirin and other medicines which can thin the blood (including clozapine, used to treat certain mental disorders). **Prizma Solution** may alter the effect of these medicines on the blood. If **Prizma Solution** treatment is started or stopped when taking warfarin, your doctor will need to perform certain tests in order to adjust an appropriate dosage of **Prizma Solution** and will monitor your condition more frequently.
- Cyproheptadine (for allergy); this medicine reduces the effectiveness of **Prizma Solution**.
- Medicines that lower sodium levels in the blood (including diuretics, desmopressin, carbamazepine and oxcarbazepine); because these medicines in combination with **Prizma Solution** may increase the risk of sodium levels in the blood becoming too low.
- Antidepressants such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs) or buspirone, mefloquine or chloroquine (used to treat malaria), tramadol (to treat pain) or antipsychotics such as clozapine, phenothiazines or butyrophenones; use of these medicines together with **Prizma Solution** may increase the risk of seizures.
- Medicines that affect the CYP2D6 enzyme such as: flecainide, propafenone, nebivolol or encainide (for treatment of heart problems), carbamazepine (for treatment of epilepsy), atomoxetine (for treatment of attention deficit hyperactivity disorder) or tricyclic antidepressants (for example, imipramine, desipramine and amitriptyline) or risperidone (for treatment of schizophrenia); **Prizma Solution** may change the blood concentration of these medicines. When used with **Prizma Solution**, your doctor will reduce the dose of these medicines.

Use of the medicine and food

You can take the medicine with or without food.

Use of the medicine and alcohol consumption

You should avoid consuming alcohol while taking the medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to get pregnant, ask your doctor or pharmacist for advice before taking the medicine.

Pregnancy

Consult with your doctor as soon as possible if you are pregnant, if you might be pregnant, or if you are planning to become pregnant.

In babies whose mothers took this medicine during the first few months of pregnancy, there have been some studies describing an increased risk of birth defects of the heart. In the general population, the risk of a congenital heart defect is 1 in 100 babies. Taking fluoxetine during pregnancy increases the risk of a congenital heart defect to 2 in 100 babies.

Taking medicines like fluoxetine during pregnancy, particularly the last three months of pregnancy, increases the risk of dangerous conditions developing in the newborn, called persistent pulmonary hypertension (PPHN), which makes the baby breathe faster and appear bluish. These symptoms usually appear during the first 24 hours after birth. If any of these symptoms appear in your baby, or if you are concerned about your baby's health, refer to a doctor immediately.

It is preferable not to use **Prizma Solution** during pregnancy unless the benefit outweighs the risks involved. Therefore, you and your doctor will decide to gradually stop use of **Prizma Solution** if you are pregnant or when you are planning to become pregnant.

Caution should be exercised when the medicine is taken during pregnancy, especially during the last months of pregnancy and before giving birth, since the following symptoms have been reported in newborn babies: irritability, chills/tremor, muscle weakness, persistent crying and difficulty suckling or sleeping.

If you are taking **Prizma Solution** close to the end of the pregnancy, there could be an increased risk of heavy vaginal bleeding shortly after delivery, especially if you have a history of bleeding. Inform the doctor that you are taking **Prizma Solution** so he can advise you.

Breastfeeding

Fluoxetine is secreted into breast milk and may affect your baby. You should only breastfeed if it is necessary. If continuation of breastfeeding is decided upon while using the medicine, the doctor may reduce the dose of the medicine.

Fertility

Fluoxetine has been shown to affect the quality of sperm in animal studies. Theoretically, taking the medicine could affect fertility, but such impact on human fertility has not been observed yet.

Driving and using machines

Prizma Solution has a negligible effect on the ability to drive or operate machines. However, psychiatric medications may have effects on motor skills and/or judgment. Therefore, consult your doctor or pharmacist before driving or using machines. Do not drive and/or use machines until you are sure that your ability to function is not impaired as a result of taking **Prizma Solution**.

Important information about some of the ingredients of the medicine

Prizma Solution contains sucrose (a type of sugar). If you have been told by your doctor that you cannot tolerate certain types of sugars (intolerance to some sugars), consult your doctor before starting to use the medicine. If you are diabetic (diabetes mellitus), this comment also applies to you.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

Adults

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

- **Depression** – The recommended dosage is 5 ml of solution (20 mg) per day. Your doctor may change the dose as needed within 3-4 weeks of starting treatment. The dose may be gradually increased to a maximum of 20 ml (80 mg) per day. The dosage should be increased under surveillance, to ensure that you receive the lowest effective dosage. You may not feel an improvement immediately after starting treatment with the medicine. A few weeks from the beginning of treatment usually elapse until there is an improvement in the symptoms of depression. Patients suffering from depression need to be treated for at least 6 months.
- **Bulimia nervosa** – The recommended dosage is 15 ml (60 mg) per day.
- **Obsessive compulsive disorder (OCD)** – The recommended dosage is 5 ml (20 mg) per day. The doctor may change the dosage, if necessary, after two weeks of treatment. The dose may be gradually increased to a maximum of 20 ml (80 mg) per day. If there is no improvement within 10 weeks, the doctor will consider changing the treatment.
- **Elderly** – Increase the dosage with extra caution and the daily dosage is generally up to 10 ml (40 mg). The maximum dosage is 15 ml (60 mg) per day.
- **Liver function disorders** – If you have liver function disorders or are using other medications that might affect **Prizma Solution**, the doctor may decide on a lower dosage or instruct you to take **Prizma Solution** once in two days.

Use in children and adolescents 8 to 18 years of age suffering from depression

Treatment should be initiated and supervised by a specialist. The starting dosage is 10 mg/day fluoxetine (as hydrochloride). After 1-2 weeks, the doctor may increase the dosage to 20 mg/day. Increase the dosage with caution to be sure that you receive the lowest effective dosage. Low-weight children may need lower dosages. If there is a satisfactory response to treatment, the doctor will assess the need for treatment beyond 6 months. If there is no improvement within 9 weeks, the doctor will reassess your treatment.

Do not exceed the recommended dosage!

Measure the appropriate amount in the measuring cup and drink the solution.

If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. The symptoms of overdose include: nausea, vomiting, convulsions, heart problems (such as irregular heart rate and cardiac arrest), lung function problems and mental status changes ranging from agitation to coma.

If you forget to take the medicine

- Do not worry; take a dose the next day at the usual time, but never take two doses together.
- Taking the medicine at the same time each day will help you remember to take it.

Adhere to the treatment regimen as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

- **Do not stop** taking the medicine without consulting a doctor even if your health has improved.
- Make sure you have enough medicine for the treatment period.

If you stop taking the medicine, withdrawal symptoms may occur, including: dizziness; tingling feelings (pins and needles); sleep disorders (vivid dreams, nightmares, inability to sleep); feeling restless and nervous; unusual fatigue or weakness; anxiety; nausea or vomiting; tremor; headaches.

Most often, the withdrawal symptoms after stopping **Prizma Solution** are mild and disappear after a few weeks. If you experience withdrawal symptoms, refer to the doctor.

Your doctor will help you reduce the dose of the medicine gradually, over the course of a week or two, in order to reduce the chance of withdrawal symptoms.

Do not take medicines in the dark! Check the label and the dose each time you take 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, use of **Prizma Solution** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

- Cases of suicidal thoughts and suicidal behaviors have been reported during treatment with **Prizma Solution** or in the early stages after stopping the medicine. If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming and/or killing yourself. This effect may be increased when first starting treatment with antidepressants, since it takes time for these medicines to have an effect (usually about two weeks but sometimes longer).

You may think like this more frequently if:

- You had a tendency to thoughts of self-harm and/or suicidal thoughts before starting treatment.
- You are a young adult. Information from clinical trials has shown that the likelihood of developing suicidal behavior in young adults under the age of 25, with psychiatric disorders treated with antidepressants, is higher.

If you have thoughts of self-harm or suicidal thoughts, **contact your doctor or go to a hospital immediately** (see section 2 "Thoughts of suicide and worsening of your depression"). **You may find it helpful to tell a family member 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 behavior.

- In case of an allergic reaction, including a rash, itching, swelling of the lips, tongue, eyes, or difficulty breathing, **stop taking the medicine and contact a doctor immediately**.
- If you experience restlessness and are unable to sit or stand still (akathisia), increasing the dose of **Prizma Solution** will cause worsening of the symptoms – **contact your doctor.**
- **Contact your doctor immediately** if your skin turns red or you develop a skin reaction that includes blistering or peeling of the skin (very rare).

Very common side effects – effects occurring in more than one in ten users – insomnia, headaches, diarrhea, nausea and vomiting, and fatigue.

Some patients experience:

- A combination of several symptoms (also known as "serotonin syndrome") that include unexplained fever accompanied by rapid breathing or rapid heartbeat, sweating, muscle stiffness or tremor, confusion, irritability or drowsiness (rarely).
- Feeling of weakness, drowsiness or confusion, especially in the elderly and elderly people taking diuretics.
- Prolonged and painful erection.
- Nervousness and restlessness.
- Heart problems such as fast or abnormal heart rate, fainting, tendency to falls or dizziness while standing up – this may indicate dysfunction of the heart.

If you experience any of the above symptoms, contact your doctor immediately.

Additional side effects:

The following side effects have been reported in people taking **fluoxetine**:

Common side effects – effects occurring in 1-10 users out of 100:

Lack of feeling of hunger, weight loss; nervousness, anxiety; restlessness, problems with concentration; feeling stressed; decreased libido or problems with sexual function (including difficulty maintaining an erection); sleep problems, unusual dreams, tiredness or sleepiness; dizziness; changes in the sense of taste; uncontrollable shaking; blurred vision; sensation of rapid and irregular heartbeat; flushing; yawning; indigestion, vomiting; dry mouth; rash, hives, itching of the skin; increased sweating; joint pain; frequent urination; unexplained vaginal bleeding; shaking and chills.

Uncommon side effects – effects occurring in 1-10 users out of 1,000:

Depersonalization disorder; strange thoughts; an extreme feeling of happiness; difficulty experiencing orgasm; thoughts of self-harm or suicidal thoughts; tooth grinding; muscle twitching, involuntary movements or problems with balance or co-ordination; memory problems; enlarged pupils; ringing in the ears; low blood pressure; shortness of breath; bleeding from the nose; difficulty swallowing; hair loss; an increase in the tendency for bruises; unexplained bruising or bleeding; cold sweat; difficulty urinating; feeling of heat/cold; abnormal liver function test results; vomiting blood or the presence of blood in the stool.

Rare side effects – effects occurring in 1-10 users out of 10,000:

Low level of salts in the blood; decreased platelets in the blood which increases the risk of bleeding and bruising; decreased white blood cell count; difficulty breathing; uncharacteristic unrestrained behavior; involuntary movements; disturbing thoughts; hallucinations; restlessness; panic attacks; confusion; stuttering, aggression, convulsions; vasculitis, rapid swelling of the neck, face, mouth and/or throat; sore throat; esophageal pain; jaundice; health-related problems; sensitivity to sunlight; muscle pain; problems passing urine; secretion of milk from the breast; severe skin reaction known as Stevens-Johnson syndrome.

Side effects of unknown frequency (frequency cannot be estimated from the available data):

Redness and burning sensation of the skin, decreased sense of touch, feeling of tickling or burning in the mouth, feeling dizzy or light-headed when you stand/sit up quickly; difficulty in making voice sounds, heavy vaginal bleeding shortly after delivery (postpartum haemorrhage), see section 2 "Pregnancy" for further information on this topic.

Bone Fractures – An increased risk of bone fractures has been observed in patients taking this medicine.

In children and adolescents (8 -18 years):

In addition to the possible side effects listed above, **Prizma Solution** may slow growth or possibly delay sexual maturity. Behaviors associated with suicide (suicide attempt, suicidal thoughts), hostility, mania and nose bleeds have also been reported, usually in children.

Most of the side effects mentioned are likely to go away with continued treatment.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" 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 "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?

- 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 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 bottle. The expiry date refers to the last day of that month.
- Store below 25°C and in a place protected from light.
- Can be used for 3 months after first opening.

6. FURTHER INFORMATION

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

Sucrose, glycerol, benzoic acid, purified water.

What the medicine looks like and the contents of the pack:

The preparation comes in a glass bottle containing 120 ml of solution. The carton package contains the preparation bottle and a measuring cup. The solution is clear and transparent-yellow in color.

Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162 93 35206 00

Revised in October 2023 according to MOH guidelines.

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