

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

The medicine is dispensed with a doctor's prescription only

## Sorbon 10 Tablets

### Composition:

Each **Sorbon 10** tablet contains:  
Buspirone HCl 10 mg.

For the list of inactive and allergenic ingredients in the preparation, see section 6 "Further information" and section 2 "Before using the medicine".

**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 to treat 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.

**This medicine is not usually intended for children and adolescents below the age of 18.**

**It is advisable to have someone close to you read this leaflet.**

### 1. WHAT IS THE MEDICINE INTENDED FOR?

**Therapeutic activity:** Short-term treatment of anxiety.

**Therapeutic group:** Azapirone anti-anxiety agents.

### 2. BEFORE USING THE MEDICINE

**Do not use the medicine if:**

- You are sensitive (allergic) to buspirone or to any of the additional ingredients contained in the medicine (see section 6 "Further information").
- You have epilepsy.
- You suffer from severe kidney or liver diseases.
- You are pregnant or breastfeeding.

### Special warnings regarding use of the medicine

**Before treatment with Sorbon 10, tell the doctor if:**

- You suffer, or have suffered in the past, from impaired liver or kidney function.

- You suffer, or have suffered in the past, from drug dependence.
- You are being treated with benzodiazepines (e.g., nitrazepam or temazepam) or with other sedatives and/or other hypnotics. These medicines should be stopped gradually before starting to use **Sorbon 10**.
- You suffer from acute narrow-angle glaucoma.
- You suffer from myasthenia gravis, a disease characterized by muscle weakness, difficulty chewing or swallowing and speech disturbances.

### Drug interactions

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking:

- Monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine and tranylcypromine, used to treat depression).
- The Hypericum herb (St. John's wort), nefazodone, the amino acid L-tryptophan, fluvoxamine, trazodone (for treatment of depression).
- Selective serotonin re-uptake inhibitors (SSRIs) e.g., fluoxetine and paroxetine (for treatment of depression).
- Serotonin norepinephrine re-uptake inhibitors (SNRIs) (e.g., duloxetine, venlafaxine).
- Tricyclic antidepressants (e.g., amitriptyline and clomipramine).
- Haloperidol and lithium (for treatment of psychiatric illnesses).
- Calcium channel blockers e.g., diltiazem and verapamil (to treat hypertension).
- Rifampicin (to treat tuberculosis).
- Triptans e.g., sumatriptan (to treat migraine).
- Tramadol (to treat pain).
- Baclofen (a muscle relaxant).
- Lofexidine (for withdrawal).
- Nabilone (to treat nausea and vomiting).
- Antihistamines (to treat allergies).
- Erythromycin, itraconazole, linezolid (to treat infections).
- Benzodiazepines (e.g., nitrazepam or temazepam) or other sedatives and/or other hypnotics.
- Diltiazem (to treat angina pectoris).
- Digoxin (to treat heart failure).
- Phenobarbital, phenytoin, carbamazepine (medicines for epilepsy).
- Cimetidine (to treat stomach ulcer).
- Diazepam (to treat anxiety).
- Warfarin (anticoagulant).

### Use of the medicine and food

Consult the doctor before eating grapefruits or drinking grapefruit juice during the course of treatment with the medicine.

The medicine can be taken with or without food, but be consistent about the way you choose to take the medicine.

### Use of the medicine and alcohol consumption

**Do not drink wine** or alcoholic beverages during the course of treatment with the medicine.

### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant, or are planning to become pregnant, consult the doctor or pharmacist before taking the medicine.

Do not use the medicine when you are pregnant or breastfeeding. The medicine has known effects on the development of the baby/fetus. Consult the doctor or pharmacist before taking the medicine.

### Children and adolescents

This medicine is not usually intended for children and adolescents below the age of 18.

### Driving and using machinery

Use of this medicine may cause sleepiness or dizziness and therefore, caution is required when driving a car, operating dangerous machinery and when engaging in any activity which requires alertness. Before driving and operating machinery, be sure that the medicine does not affect you. If you are uncertain, consult the doctor or pharmacist before driving or using machinery.

### Important information regarding some of the ingredients of the medicine

If you suffer from an intolerance to certain sugars, refer to a doctor before taking **Sorbon 10** since the medicine contains a sugar called lactose, which can cause an allergic reaction in people sensitive to lactose.

### 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 about the dosage and treatment regimen of the preparation.

**Children and adolescents** – this medicine is not usually intended for children and adolescents below the age of 18.

If you suffer from kidney or liver dysfunction, the doctor may decide on a lower dosage for you.

Swallow the medicine with water.

If necessary, the tablet can be halved for immediate use. There is no information about crushing or chewing the tablet.

Try to take the medicine at set times each day.

**If you accidentally take a higher dosage,** or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Symptoms of overdose include nausea and feeling sick, headache, dizziness, sleepiness, ringing or buzzing in the ears, restlessness, constriction of the pupils, digestive problems, slow heartbeat, low blood pressure, convulsions and extrapyramidal symptoms (difficulty speaking or swallowing, loss of balance, "frozen" facial expression, shuffling, stiffness in the limbs, trembling of the hands or fingers).

**If you forget to take this medicine** at the required time, take a dose as soon as you remember; but if it is almost time to take the next dose, skip the forgotten dose and take the next dose at the usual time. Never take a double dose!

Adhere to the treatment regimen as recommended by the doctor.

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

**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 **Sorbon 10** 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.

**Stop using the medicine and refer to the doctor immediately if you experience:**

- Serotonin syndrome: you are taking selective serotonin re-uptake inhibitors (SSRIs) and you suffer from symptoms of serotonin syndrome, which include confusion, restlessness, sweating, tremor, chills, hallucinations (seeing things or hearing sounds that do not exist), sudden muscle cramps or a fast heartbeat.
- Allergic reaction: itching, breathing difficulties or swelling of the face, lips, throat or tongue, allergic reactions that cause itching and swelling of the skin.
- Hallucinations and psychoses.

- Seizures or convulsions.
- Restricted vision.
- Fainting or loss of consciousness.

**The above described side effects are very rare (may affect up to 1 in 10,000 patients).**

**Very common side effects (may affect more than one in 10 patients):**

Dizziness, headaches, sleepiness.

**Common side effects (may affect one in 10 patients):**

Nervousness, insomnia, concentration problems, depression, confusion, sleeping disturbances, anger, excitement, stinging or prickling sensations, blurred vision, coordination problems, tremor, ringing or buzzing in the ears, accelerated heartbeat, chest pain, nasal congestion, sore throat, nausea and feeling sick, abdominal pain, constipation, dry mouth, diarrhea, cold sweat, rash, pain in the muscles, tendons, ligaments and bones, mental and physical tiredness.

**Rare side effects (may affect up to 1 in 1,000 patients):**

Bruising, itchy skin rash caused by an allergic reaction – pale or red irregular raised blisters accompanied by severe itching (urticaria).

**Very rare side effects (may affect up to 1 in 10,000 patients):**

Feeling that the mind is separated from the body, emotional instability, sudden onset of symptoms of sickness, extrapyramidal symptoms [tremor, speech difficulties, inability to stand or sit quietly (akathisia), dystonia (muscle spasms of the neck, shoulders or body, which affects posture)], anxiety, distress, muscle rigidity, involuntary movements/uncontrollable jerky movements, partial or complete memory loss, lack of muscle control and lack of coordination, difficulty in controlling movements, tremor, stiffness and shuffling, restless leg syndrome, restlessness, difficulty urinating, increased milk secretion from the breast.

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

### Reporting side effects

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](http://www.health.gov.il)), that directs you to the online form for reporting side effects. 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 safe 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 package. The expiry date refers to the last day of that month.

Store below 25°C and in a place protected from light.

### 6. FURTHER INFORMATION

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

Microcrystalline Cellulose; Lactose; Sodium Starch Glycolate; Magnesium Stearate; Colloidal Silicon Dioxide.

**What the medicine looks like and the contents of the package:**

**Sorbon 10** is packaged in trays (blisters) inserted into a carton package. Each package contains 20, 30 or 100 tablets. Not all package sizes may be marketed.

**Sorbon 10** tablets are round, white, biconvex and with a score line on one side.

### The preparation contains lactose

Each **Sorbon 10** tablet contains 111.4 mg lactose.

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

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

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 100 07 27954 01

Revised in July 2021 according to MOH guidelines.