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

The medicine is dispensed with a doctor's prescription only

Bonserin®
Tablets

Active ingredient:
Each tablet contains: 30 mg mianserin hydrochloride.

For the list of the additional ingredients, see section 6. See also "Important information about some of the medicine's ingredients" in section 2.

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

Antidepressants increase the risk of suicidal behavior and thoughts in children, adolescents and young adults.

When starting the treatment with the medicine, the patients of all ages and their relatives, need to pay attention to behavioral changes such as: worsening of the depression, suicidal thoughts, aggression and so forth.

If changes such as these occur, refer to the doctor immediately.

1. What is the medicine intended for?

Bonserin is a medicine indicated for the treatment of depression.
Therapeutic Group: tetracyclic antidepressant.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).
- You are taking medicines from the monoamine oxidase inhibitors group (MAOIs), or if you took such a medicine during the past 2 weeks (see section 2 "Drug interactions").
- You suffer from severe liver problems.
- You suffer from mania (a mood disorder characterized by a high level of excitement and activity).
- You are breastfeeding.

Special warnings regarding the use of the medicine:

- **Suicidal thoughts and worsening of depression or anxiety**: If you are depressed and/or suffer from anxiety, you may have thoughts of harming yourself or even suicide. This situation may intensify at the beginning of treatment with antidepressants, since it takes time for the medicine to work (usually about two weeks, but sometimes even longer). The frequency of this effect increases in the following cases:
  - If you previously had thoughts about harming yourself or of suicide.
  - If you are under the age of 25. Studies have shown an increased risk of suicidal behavior in patients under the age of 25 years, with mental health conditions, who were treated with antidepressants.

Refer immediately to a doctor or hospital if you have thoughts of harming yourself or of suicide.
It is also recommended to share your condition with friends and family and to ask them to also watch out for worsening of your condition or changes in your behavior.

- **Elderly patients,** during treatment with the medicine, may experience agitation, confusion, drop in blood pressure when standing up (causing dizziness, spinning or fainting).
- The medicine is generally not intended for children and adolescents under the age of 18. It was found during clinical studies that children and adolescents under the age of 18 who took similar antidepressants were at a higher risk of side effects, such as attempted suicide, suicidal and hostile thoughts (mainly aggression, oppositional behavior and anger). Nonetheless, the doctor may prescribe this medicine if he thinks that it will be beneficial for the patient. See also section "Use in children". In any case you can refer back to the doctor to talk to him about the treatment.
- If you are to have surgery or treatment (including dental treatment) which requires use of an anesthetic, tell the doctor you are taking Bonserin.
- Do not use this medicine frequently, or for a long period, without consulting the doctor.
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

Before starting treatment with Bonserin tell the doctor:

- If you suffer or have suffered in the past from impaired function of the liver and the kidneys.
- If you recently had a heart attack (myocardial infarction) or if you suffer or have suffered in the past from heart problems, such as: heart block, heart rhythm disturbances or heart failure (when the heart does not provide the amount of blood the body requires). In this case the doctor may monitor the heart function.
- If you suffer or have suffered in the past from suicidal thoughts, diabetes, as your doctor may change the medicine dosage accordingly, glaucoma (an eye disease) and particularly narrow-angle glaucoma, impaired prostate function, symptoms of bladder neck obstruction (e.g. in the case of an enlarged prostate gland), urinary retention (difficulty urinating) or a tumor in the adrenal gland (pheochromocytoma).
- If you suffer or have suffered in the past from epilepsy, if you had an epileptic seizure (a fit) in the past, or may undergo an epileptic seizure due to the following reasons: brain injury, taking or stopping to take medicines for mental health treatment (which can cause a feeling of sleepiness or attacks as a side effect), if you are in withdrawal from alcohol or from medicines to control seizures (anticonvulsants).
- If you are pregnant (see the "Pregnancy and breastfeeding" section).
- If you suffer from manic depression.

Drug interactions:
If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines, please consult with the doctor or pharmacist):

- Antidepressants from the monoamine oxidase inhibitors group (MAOIs), such as tranylcypromine, moclobemide or phenelzine: Do not use Bonserin if you are taking medicines from the monoamine oxidase inhibitors group (MAOIs), or if you took such a medicine during the past two weeks. Wait at least 14 days after you have stopped treatment with monoamine oxidase inhibitors before starting treatment with Bonserin. Wait one to two weeks from stopping to take Bonserin to taking monoamine oxidase inhibitors. Likewise, wait at least one week after you have stopped taking Bonserin to taking moclobemide.
- Medicines that affect the central nervous system [e.g. medicines for calming, for sleeping, antianxiety (such as diazepam), antipsychotic medicines (for treatment of mental health conditions), other antidepressants, medicines for the treatment of Parkinson's (such as procyclidine), antihistamines for allergies (such as diphenhydramine), narcotic painkillers, and anesthetics].

- Medicines for the treatment of epilepsy, such as: phenytoin, carbamazepine, barbiturates (phenobarbital, primidone).
- Medicines to prevent blood clotting, e.g. warfarin.
- Medicines to lower blood pressure, such as: diazoxide, hydralazine and nitroprusside. When taken with Bonserin, the activity of these medicines may be increased. The doctor may want to check your blood pressure more often.
- Medicines for the treatment of glaucoma, such as apraclonidine or brimonidine, or eyedrops to dilute the pupils (such as atropine).
- Sublingual nitrates (tablets placed under the tongue) to treat chest pains. When taken with Bonserin the activity of these medicines may be weakened.
- Antimuscarinic medicines that may be used for treatment of kidney problems (such as tiotropium and ipratropium), for the treatment of bowel spasms (such as hyoscine and dicycloverine), or medicines for the treatment of problems with urinating (such as bethanechol). When taken with Bonserin, the activity of these medicines may be increased.
- Artemether with lumefantrine for the treatment of malaria.
- Atomoxetine for the treatment of attention deficit hyperactivity disorder (ADHD).
- Sibutramine, used to help weight loss.

Use of this medicine and alcohol consumption: Do not drink wines or alcoholic beverages during the treatment period with this medicine. Alcohol may increase the drowsiness effect of the medicine.

Pregnancy and breastfeeding:

- Do not use the medicine if you are pregnant, think you may be pregnant or are planning a pregnancy, unless your doctor recommended that you do so. There is limited information on the use of the medicine during pregnancy.
- Do not use the medicine if you are breastfeeding. If the doctor instructs you to use the medicine, stop breastfeeding.

Driving and use of machinery: the most common side effect is drowsiness (which may intensify with use of alcohol), particularly during the first few days of treatment. The use of this medicine may cause blurred vision, impair alertness and cause drowsiness also during the day. If you feel this way, do not drive or operate machinery. In any case, caution must be exercised when driving a vehicle, operating dangerous machinery and in any activity that requires alertness.

Use in children:

This medicine is not generally intended for children and adolescents under the age of 18.
In children and adolescents under the age of 18, inform the doctor of any side effect or worsening of a side effect. There is no information about the long-term effects regarding safety in relation to growth, maturation and cognitive and behavioral development in this age group. See also the section "Warnings".

Important information about some of the medicine's ingredients:

The tablets contain lactose. If you are sensitive to lactose, or if you have an intolerance to certain sugars, inform the doctor before taking this medicine (see section 6).

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not certain about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.
Use this medicine at set times as determined by the attending doctor.
The standard dosage is usually:

Adults: initial dosage of 30 mg a day, in divided doses or as a single dose at bedtime. If necessary, the doctor will increase the dosage gradually. The maintenance dosage range is usually 30 mg to 90 mg a day.
Elderly patients: For this population it is recommended to take the medicine as one dose at bedtime, unless otherwise instructed by the doctor. The doctor may also decide that a reduced dosage is required. If a higher dosage is required, it should be done under medical supervision.

Do not exceed the recommended dosage.
Swallow the medicine with water.
The tablet may be halved according to the scored line.
If you halve the tablet in order to make it easier to swallow, make sure to take both halves of the tablet.
Do not chew or crush the tablet.

Tests and follow-up: during the treatment period with this medicine, blood tests (including liver function test) and general checkups, should be carried out.
If you have accidentally taken a higher dosage: If you (or any other person) have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room, and bring the medicine package with you. Overdose symptoms include: nausea, vomiting, dry mouth, abnormally small or large pupils, involuntary eye movements, dizziness, lack of coordination, difficulty moving, drowsiness, convulsions, coma, abnormal heartbeats (too fast or too slow), a rise or drop in blood pressure (which might cause a feeling of faintness).
If you forgot to take the medicine: if you forgot to take this medicine at the designated time, take a dose as soon as you remember. If it is almost time for the next dose, wait until this time and carry on as usual. Do not take a double dose to make up for a forgotten dose!
Adhere to the treatment as recommended by the doctor. An improvement from the treatment may be felt only after 2 to 4 weeks.
If you stop taking the medicine:
Even if your state of health improves, do not stop the treatment with the medicine without consulting your doctor. The doctor will guide you how to reduce the dosage gradually to prevent side effects such as sweating, shaking, aggression, anxiety, hallucination, nausea and vomiting.

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 concerning the use of the medicine, consult the doctor or pharmacist.

4. Side Effects
As with any medicine, the use of Bonserin 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 the treatment and proceed immediately to a doctor or to a hospital emergency room in the following cases:

- Appearance of an allergic reaction whose symptoms include: swelling of the lips, face or neck that may lead to severe difficulty in breathing; skin rash or hives. This is a very severe but rare reaction.
- If you have thoughts of harming yourself or suicide, or behaviors consistent with these thoughts. See "Warnings" in section 2.
- If the following side effects occur: Convulsions, jaundice (which symptoms might include yellowing of the skin or the white of the eye), feeling of euphoria and elation or over-excitement; signs of infection such as high fever and pain, or mouth and throat inflammation, mouth ulcers, cold sores, or other signs of infection, feeling of tiredness, weakness or pallor.

Other Side Effects:

- Blurred vision, dry mouth, constipation.

- Breast changes (breast enlargement in men, nipple tenderness, milk production not during breast-feeding), liver function problems.
- Dizziness and feeling faint, caused by a drop in blood pressure when standing up from a sitting or lying position.
- Drowsiness, edema (water retention); joint problems, such as: joint diseases, swollen joints, pain and inflammation (arthritis).
- Skin rash, sweating, shaking, mental disorders such as paranoid hallucinations and mania; sexual function problems in adults; withdrawal symptoms (see section 3 "If you stop taking the medicine"); withdrawal symptoms such as irritability and agitation, may also appear in babies whose mothers received the medicine during pregnancy.

Additional Side Effects (that appear more frequently in the elderly):

- Bone marrow depression (an impairment in blood cell production which can result in anemia that can be manifested also in pallor; bruising, bleeding and increased susceptibility to infections).
- Reduction in the number of red or white blood cells (leucopenia, agranulocytosis, aplastic anemia), which can cause weakness, bruising, or increased susceptibility to infections (see details at the beginning of the section).
- Hyponatremia (low sodium level in the blood), which can cause tiredness, confusion and convulsions.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored 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) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25 °C, in the original package.

6. Additional information

In addition to the active ingredient, the tablets also contain:

Lactose, cellulose microcrystalline, pigment blend green, magnesium stearate, silicon dioxide colloidal.

Each tablet contains about 123 mg lactose.

What does the medicine look like and what does the package contain?
Round green tablets with a scored line, in blisters packages of 20 tablets.

Registration Holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.
Medicine registration number in the National Medicines Registry of the Ministry of Health:
0432826084

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