Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Bonserin

Tablets

Active ingredient:

Each tablet contains: Mianserin Hydrochloride 30 mg.

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

Read this entire leaflet carefully before 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 treating your condition. Do not pass it on to others. It may harm them, even if seems to you that their medical condition is similar to yours.

1. What is the medicine intended for?

Bonserin is a medicine intended for treatment of depression.

Therapeutic Group: tetracyclic antidepressant.

2. Before using the medicine

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for the list of inactive ingredients, please see section 6).
- Do not use Bonserin if you are taking medicines of the monoamine oxidase inhibitors group (MAOIs), or if you took such a medicine within the last two weeks.
- Do not use if you suffer from severe liver problems.
- Do not use if you suffer from mania (a mood disorder characterized by high levels of excitement and activity).
- Do not use the medicine if you are breastfeeding.

Special warnings regarding the use of this medicine:

- **Thoughts of suicide 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. These thoughts may intensify when starting 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 25 years of age. Studies have shown an increased risk of suicidal behavior in patients under 25 years of age, with psychiatric conditions, who were treated with antidepressants.

  Go immediately to a doctor or a hospital if you have thoughts of harming yourself or of suicide.

  It is also recommended to share your condition with your friends and family and to ask them to also watch out for worsening of your condition or changes in your behavior.
- **The elderly** may experience agitation, confusion, fall in blood pressure when standing up (causing dizziness, light-headedness or fainting) when taking this medicine.
- This medicine is not usually intended for children and adolescents under 18 years of age. It was observed during clinical trials that children and adolescents under 18 years of age who took similar antidepressants had a high risk of side effects such as attempted suicide, suicidal thoughts and hostility (principally aggression, oppositional behavior and anger). Nevertheless the doctor may prescribe this medicine if he/she thinks that it will be beneficial for the patient. See also section 'Use in children'.
- In any case you can go back to the doctor to talk to him/her about the treatment.
- If you are to have surgery or treatment (including dental treatment) which requires an anesthetic, tell the doctor you are taking Bonserin, since the combination of the medicines may make your blood pressure drop or alter your heart rate.

- Do not use this medicine frequently, or for a long period, without consulting your doctor.
- If you are sensitive to any type of food or medicine, inform the doctor before taking this medicine.

Before starting treatment with Bonserin tell your doctor:

- If you suffer or have suffered in the past from impaired function of the: liver, kidneys or prostate gland.
- If you have recently had a heart attack or if you suffer or have suffered in the past from heart problems.
- If you suffer or suffered in the past from thoughts of suicide, diabetes, glaucoma (eye disease), epilepsy, brain damage or tumor of the adrenal gland (pheochromocytoma)
- If you are in withdrawal from alcohol or anticonvulsants (medicines to prevent seizures).

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Antidepressants of the monoamine oxidase inhibitors group (MAOIs) such as moclobemide or phenelzine: Do not use Bonserin if you are taking medicines of the monoamine oxidase inhibitors group (MAOIs), or if you took such a medicine within the last two weeks. Wait at least 14 days after you have stopped treatment with monoamine oxidase inhibitors before starting the Bonserin treatment. Likewise, wait at least one week after you have stopped taking Bonserin before taking moclobemide.
- Medicines that affect the central nervous system (e.g. sedatives, sleeping pills, antianxiety medicines such as diazepam, antipsychotic medicines (for treatment of psychiatric problems), other antidepressants, medicines for treatment of Parkinson's disease, antihistamines (against allergies), narcotic painkillers and anesthetics).
- Medicines for treatment of epilepsy such as: phenytoin, carbamazepine, barbiturates (phenobarbital, primidone).
- Medicines to prevent blood clotting e.g. warfarin.
- Medicines to lower blood pressure: your doctor may want to check your blood pressure more often.
- Medicines for treatment of glaucoma such as apraclonidine or brimonidine.
- Sublingual nitrates (tablets placed under the tongue) to treat chest pains.
- Antimuscarinic medicines, artemether with lumefantrine (against malaria), atomoxetine.

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

Pregnancy and breastfeeding:

- Do not use the medicine if you are pregnant or planning to become pregnant, unless your doctor recommended that you do.
- Do not use the medicine if you are breastfeeding.

Driving and use of machinery: 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 performing any activity that requires alertness.

Use in children:

This medicine is not usually intended for children and adolescents under 18 years of age.
In children and adolescents under 18 years of age, you must inform the doctor of any side effect or worsening of a side effect. There is no data about the long-term effects on the safety aspect in relation to growth, maturation and cognitive and behavioral development in this age group. See also the warnings section.

Important information about some of the medicine's ingredients:

The tablets contain lactose. If you are sensitive to lactose, inform the doctor before taking this medicine (please see section 6).

3. How to use this medicine?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.
The dosage and the manner of treatment will be determined by the doctor only.
Use this medicine at set intervals as determined by the attending doctor.
The standard dosage is usually:
Adults: initial dosage of 30 mg a day, either in divided doses or as a single dose at bedtime. Your doctor may increase the dosage gradually if necessary. The maintenance dose range is usually 30 mg to 90 mg a day.
Elderly patients: For these patients, it is recommended to take the medicine as a single dose at bedtime, unless otherwise instructed by the doctor. The doctor may also decide that a reduced dosage is required. If an increase of dose is required, it must 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 the swallowing easier, make sure to take the two halves of the tablet.
Do not chew or crush the tablet.

Tests and follow-up: during treatment with this medicine, blood tests (including liver function test) and general checkups must be carried out.
If you have accidentally taken a higher dosage: if you (or anyone else) took an overdose or if a child accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Overdose symptoms include: nausea, vomiting, dry mouth, abnormally large or small pupils, involuntary eye movements, dizziness, lack of coordination, difficulty moving, drowsiness, convulsions, coma, abnormal heart rate (too fast or too slow), increase or decrease 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 set time, take a dose as soon as you remember. If it is almost time for the next dose, wait until then and carry on as usual. Do not take a double dose to make up for a forgotten dose!
Continue with 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 this medicine without consulting your doctor. Your doctor will instruct you how to reduce the dosage gradually in order 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 any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side Effects
Like any medicine, the use of Bonserin may cause side effects in some users. If the side effects persist or they are bothersome or get worse, consult your doctor. Do not be alarmed while 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:

- Upon the occurrence of an allergic reaction whose symptoms include: swelling of the lips, face or neck which may lead to severe difficulty in breathing; rash or urticaria (hives). This is a very serious but rare reaction.

- If you have thoughts of harming yourself or of suicide. See the warnings section.

Contact your doctor immediately if the following serious side effects occur:
Convulsions, jaundice (whose symptoms might include yellowing of the skin and the white of the eyes), feeling of euphoria and elation or over-excitement; signs of infection such as fever and pain or inflammation in the mouth and throat.

Additional side effects:
- Blurred vision, dry mouth, constipation.
- Breast changes (breast enlargement in men, tender nipple, milk production not during breast-feeding); liver problems.
- Dizziness and feeling faint, caused by a fall in blood pressure when you stand up from a sitting or lying position.
- Drowsiness, edema (water retention); joint problems such as joint diseases, pain, inflammation (arthritis).
- Skin rash, sweating, shaking, psychiatric disorders such as paranoid delusions and mania; sexual dysfunction; withdrawal symptoms; withdrawal symptoms may also occur 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 may cause anemia manifested also as pallor; bruising, bleeding and increased susceptibility to infections).
- Reduction in the number of red or white blood cells (leucopenia, agranulocytosis, aplastic anemia), which may cause weakness, bruising or increased susceptibility to infections.
- Hyponatremia (low sodium level in blood), which may cause tiredness, confusion, muscle twitching, convulsions, coma.

If you experience any side effects that are not mentioned in this leaflet or if there is any change in your general feeling, consult the doctor immediately!

5. How to store the medicine?
- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach 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 the following inactive ingredients:
Lactose, cellulose microcrystalline, pigment blend green, magnesium stearate, silicon dioxide colloidal.
Each tablet contains approximately 123 mg lactose.

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

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

This leaflet was checked and approved by the Ministry of Health in March 2015.
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