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

This medicine is sold with a doctor's prescription only

Bondormin
Tablets

Active ingredient:
Each tablet contains 0.25 mg brotizolam.
For a list of the other 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, please refer to your doctor or pharmacist.
This medicine has been prescribed for your treatment. 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.

Introduction to the Patient Leaflet for Benzodiazepines
This medicine belongs to the group of benzodiazepines, which has special properties requiring the utmost caution while using it.
Close medical follow-up is very important while taking this medicine.
When taking this medicine, make sure to refer to your doctor after two weeks, since treatment is intended for short periods of time only.
Prolonged use of this medicine may cause a reduction in its effect.
Prolonged use may cause a severe effect of dependence, making it difficult for the patient to discontinue taking the medicine and therefore, discontinuation of the medicine should be done gradually, according to the doctor's instructions.
Uncontrolled discontinuation of treatment is accompanied by withdrawal symptoms, such as: tension, nervousness, confusion, tremor, insomnia, abdominal pains, vomiting, nausea, sweating, spasms, cramps and muscle pain.
Sometimes prolonged use of the medicine may cause changes in behavioral patterns and nagging thoughts.
Especially in the elderly, caution is recommended when walking, since the medicine impairs alertness and sometimes coordination of body movements, thus raising concern about stumbles or falls.

Taking this medicine along with medicines from the opioid group, other medicines which depress the central nervous system (including drugs) or alcohol may cause a feeling of profound drowsiness, difficulty breathing (respiratory depression), coma and death.

1. What is the medicine intended for?
Bondormin is a medicine which is intended for the treatment of insomnia.
Therapeutic group: benzodiazepines

2. Before you take the medicine
Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, to other benzodiazepines, or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).

- You are pregnant or breastfeeding.
- You suffer from severe respiratory insufficiency, sleep apnea, severe liver insufficiency, myasthenia gravis, or if you suffer or have suffered in the past from dependency on medicines, drugs or alcohol.
- You suffer from intoxication from alcohol, sleeping medicines (hypnotics), opioid analgesics, or psychiatric medicines (such as antipsychotic medicines, antidepressants, lithium).
- Do not use this medicine in children and adolescents under the age of 18.

Special warnings regarding the use of this medicine:

Prolonged use may cause dependence! The risk of dependency on this medicine is increased when taking a high dosage and with a prolonged treatment period. In addition, the risk of developing dependence is higher in patients who have a history of dependencies on medicines or alcohol. If a dependency on the medicine exists, sudden discontinuation will be accompanied by withdrawal symptoms (see section **'If you stop taking the medicine'**).

- Do not use this medicine often or for prolonged periods without consulting your doctor.
- Taking the medicine daily for several weeks may cause a decrease in its effectiveness.
- Bondormin has a muscle-relaxing effect, which may increase the risks for falls. Use with caution in the elderly.

Before treatment with Bondormin tell your doctor:

- If you suffer or have suffered in the past from impaired function of the: respiratory system, liver. In such cases, your doctor may recommend a reduced dosage.
- If you suffer or have suffered in the past from depression or suicidal thoughts.
- If you are sensitive to any type of food or medicine.

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 (please note that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using any of these medicines, please consult with your doctor or pharmacist):

- Medicines which affect the central nervous system (such as: sedatives, sleeping medicines, antidepressants or anti-anxiety, antipsychotics), medicines to treat epilepsy, certain antihistamines, anaesthetics, narcotic analgesics).
- Muscle relaxants, medicines for the treatment of diabetes and high blood pressure, glycosides for the treatment of heart problems (such as digoxin), hormones.
- The following medicines may cause an increase in the effectiveness of Bondormin: azole antifungals (such itraconazole, ketoconazole), macrolide antibiotics (such as clarithromycin, erythromycin), protease inhibitors (such as indinavir, nelfinavir, ritonavir), cimetidine.
- The following medicines may cause a decrease in the effectiveness of Bondormin: carbamazepine, efavirenz, St. John's wort (hypericum), nevirapine, phenobarbital, phenytoin, primidone, rifabutin, rifampicin.

- Additional medicines that may affect the activity of Bondormin: immunosuppressants (such as ciclosporin, sirolimus, tacromilus), calcium channel blockers, antimalarial medicines such as mefloquine and halofantrine, midazolam, pimozide, sildenafil, medicines for lowering cholesterol from the statins group (such as: atorvastatin, lovastatin, simvastatin), steroids (such as ethinyl-estradiol), tamoxifen, terfenadine.

Use of the medicine and food:

- Take the medicine on an empty stomach.
- Do not drink grapefruit juice during treatment.

Use of the medicine and alcohol consumption: Do not drink wines or alcoholic beverages during the treatment period with the medicine. Use of alcohol during treatment with Bondormin may cause, among other things, sedation, drowsiness and impair concentration.

Pregnancy and breastfeeding:

Do not use this medicine if you are pregnant or breastfeeding.
If you intend to become pregnant, or suspect you are pregnant, refer to the doctor.

Driving and use of machinery: The use of this medicine may impair alertness, ability to concentrate, and muscle function (especially when the duration of sleep is insufficient or in combination with medicines which affect the central nervous system). In the event that you feel effects such as those detailed, do not drive or operate machinery. In any case, caution must be exercised when driving a vehicle, operating dangerous machinery and in any activity which requires alertness.

Use in children: This medicine is not intended for children and adolescents under the age of 18.

Use in the elderly, debilitated patients, patients with liver function problems or with respiratory insufficiency: this group may be more sensitive to the effects of the medicine; therefore, it should be used with caution and with a reduced dosage. Included among the effects of the medicine, especially in the elderly, is an increase in the risk of falling as a result of muscle relaxation (see 'Introduction')

Important information about some of the medicine's ingredients:

Bondormin contains lactose. If you are sensitive to lactose, inform your doctor before taking this medicine.

3. How should this medicine be used?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.
The dosage and the manner of treatment will be determined by the doctor only.
The standard dosage is usually: 1/2-1 tablet (according to the doctor's decision), before sleep.

Do not exceed the recommended dose under any circumstance.

There is no information regarding crushing or chewing of the tablets.
Swallow the medicine with water or gradually dissolve under the tongue.
This medicine should be taken on an empty stomach.
This medicine can be halved using the score line.
Make sure to get at least 7 hours of sleep after taking the medicine, in order that you will be able to function properly after waking up (see also section 'Driving and use of machinery').

If you have accidentally taken a higher dosage: If you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you.
Symptoms of an overdose may include: drowsiness, confusion, fatigue. In severe cases, impaired coordination, decrease in muscle tension, hypotension, respiratory depression, coma (rare) and death (very rare) may also occur.

If you stop taking the medicine: Even if your state of health improves, do not stop treatment with the medicine suddenly without consulting with your doctor. This instruction is very important, especially with a medicine such as Bondormin (see 'Introduction').

- Sometimes after discontinuation of the medicine, there may be a rebound or worsening of insomnia, and also in rare cases, restlessness, mood changes, anxiety and tension. The risk for this is higher with sudden treatment discontinuation or sudden decrease in dosage.

- In addition, there may be withdrawal symptoms after sudden discontinuation of the medicine (especially if dependency on the medicine has developed) such as: headaches, muscle pain, extreme anxiety, tension, insomnia, restlessness, confusion, nervousness. In severe cases, there may be misinterpretation of reality, personality changes, lack of sensation (numbness) and tingling in the hands and feet, hypersensitivity to light, noise and touch; hallucinations, epileptic seizures. These reactions may also occur several days after discontinuation of the medicine.

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 this medicine, consult your doctor or pharmacist.

4. Side effects:

Like any medicine, the use of Bondormin may cause side effects in some users.
When side effects appear or if side effects persist or are bothersome or worsen, consult with the doctor.
Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

Refer to a doctor immediately if the following side effects appear:
Paradoxical reactions such as: restlessness, agitation, nervousness, rage, aggressiveness, increased insomnia, nightmares, hallucinations, psychoses, changes in behavioral patterns including inappropriate behavior, confusion and delirium (uncommon side-effects).

Additional side effects:
Common side effects (appear in 1-10 users out of 100): headache, feeling of dizziness (light-headedness), disturbances of the digestive system.
Uncommon side effects (appear in 1-10 users out of 1,000): nightmares, depression, changes in mood, anxiety, dependency on the medicine, emotional disturbances, behavioural changes, agitation, changes in libido, dizziness, sedation, lack of coordination and impairment of body movements coordination (ataxia), memory disturbances, dementia, mental and psychomotor impairments, vision disturbances (such as double-vision), liver disturbances (including jaundice and changes in liver function test values), dry mouth, skin reactions, muscle weakness, withdrawal symptoms and rebound or worsening of insomnia after discontinuation of the medicine, drowsiness (during the day), nervousness, increased risk of accidents and falls.
Rare side effects, (appear in 1-10 users out of 10,000): confusion, restlessness, decrease in alertness and preparedness.
If side effects appear, if one of the side effects worsens or when you suffer from side effects not mentioned in this leaflet, consult with your 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 you to the online form for reporting side effects, or by entering the link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

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 a 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.

6. Additional information

In addition to the active ingredient, the tablets also contain the following ingredients:
Lactose, corn starch, cellulose-microcrystalline, sodium starch glycolate, magnesium stearate.
Each tablet contains approximately 82 mg lactose.

What does the medicine look like and what does the package contain?
White round tablets with a score line, in blister packs of 10 or 20 tablets in a box. Not all pack sizes may be marketed.
Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.
Medicine registration number in the National Drug Registry of the Ministry of Health:
120 37 26021 12
This leaflet was checked and approved by the Ministry of Health in April 2017.

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