PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Brotizolam Teva 0.25 mg
Tablets

Composition:
Each tablet contains:
Brotizolam 0.25 mg
For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information".
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others under any circumstances. It may harm them even if it seems to you that their medical condition is similar.
Introduction
This medicine belongs to the benzodiazepines group, which has special characteristics that require extra care during use.

It is highly important to be under close medical supervision when taking this medicine. When taking this medicine, be sure to refer to the doctor after 2 weeks, since the treatment is only intended for short time periods.
Prolonged use of this medicine may cause the effect of the medicine to decrease. Prolonged use may cause a severe effect of dependence, which will make it difficult for the patient to stop taking the medicine. Therefore, you should stop taking the medicine gradually, according to the doctor's instructions.
Uncontrolled discontinuation of the treatment may be accompanied by withdrawal effects such as: stress, nervousness, confusion, tremor, insomnia, abdominal pain, vomiting, nausea, sweating, spasms, cramps and muscle pain.
Prolonged use of this medicine may sometimes cause changes in behavioral patterns and obsessive thoughts.
Especially in the elderly: care should be taken when walking, since the medicine impairs alertness and sometimes the coordination of body movements, which may lead to tripping or falling down.

Taking this medicine together with opioid medicines, with other medicines that depress the central nervous system (including drugs) or with alcohol, may cause a sensation of deep drowsiness, breathing difficulties (respiratory depression), coma and death.

1. WHAT IS THE MEDICINE INTENDED FOR?
For treatment of sleep problems.
Therapeutic class
Belongs to the benzodiazepines group.
The medicine does not treat the cause of the sleep disorders.

2. BEFORE USING 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 the preparation contains (for a list of inactive ingredients, see section 6).
- You are pregnant or breastfeeding.
- You suffer from severe respiratory insufficiency, sleep apnea syndrome, severe liver failure, myasthenia gravis, which is a disease manifested by muscle weakness.
- You suffer or have suffered in the past from dependence on medicines, illegal drugs or alcohol.
- You suffer from intoxication from alcohol, sleeping pills, opioid pain relievers or psychiatric medicines (such as antipsychotic medicines, antidepressants, lithium).
- Do not use in children and adolescents under the age of 18.

Special warnings regarding the use of the medicine:
Before treatment with Brotizolam Teva, inform the doctor if:
- You are abusing or have previously abused alcohol, illegal drugs and medicines.
- You are already being treated with Brotizolam Teva.
- You suffer or have suffered in the past from impaired function of the respiratory system, the liver. In such cases, the doctor may recommend a reduced dosage.
- You suffer or have suffered in the past from depression or suicidal thoughts.
- You are sensitive to any type of food or medicine.

Additional warnings
- Prolonged use may lead to physical and psychological dependence! The risk of dependence on the medicine increases with increased dosage and duration of treatment. Therefore, the doctor will instruct you to use the medicine for the shortest duration possible and may even arrange periodic follow-up appointments. Psychological dependence can be identified when you reach a point in which you do not want to stop using the medicine. In case there is a physical dependence on the medicine, sudden discontinuation will be accompanied by withdrawal symptoms (see section 3 – "If you stop taking the medicine"). In addition, the risk of developing dependence is higher in patients who are abusing or have previously abused medicines or alcohol (see section 3 – "If you stop taking the medicine").
- You may experience forgetfulness during the treatment with the medicine. This effect usually occurs several hours after taking the medicine. Please refer to the doctor if you experience this effect.
- If you suffer from psychosis (a severe psychiatric disease that affects behavior and self-control), Brotizolam Teva is not suitable for you.
- If you suffer from severe depression or from anxiety with episodes of severe depression, treatment with Brotizolam Teva may increase the risk of developing thoughts of self-harm or suicidal thoughts. Consult a doctor before treatment with the medicine. The doctor will closely monitor you during the treatment with Brotizolam Teva. Refer immediately to the doctor or to the hospital whenever these thoughts arise.
- Do not use this medicine frequently or for a prolonged period of time without consulting the doctor.
- Daily use for a duration of several weeks may cause a reduced effectiveness of the medicine.
- Brotizolam Teva has a muscle relaxing effect, which may increase the risk for falls. Use with caution in the elderly.

Drug interactions
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. In particular, you should inform the doctor or pharmacist if you are taking any of the following medicines (note that the following list mentions the active ingredients in the medicines. If you are not sure whether you are taking any of these medicines, please consult the doctor or pharmacist):
- Medicines affecting the central nervous system (such as: sedatives, sleep medicines, antidepressants or anti-anxiety medicines, antipsychotics, medicines for treatment of epilepsy, certain antihistamines, anesthetics, narcotic analgesics) – using these medicines during treatment with Brotizolam Teva may cause increased depression of the central nervous system.
- Opioids (strong pain relievers, drug substitutes and certain cough medicines) – concomitant use with Brotizolam Teva increases the risk of sleepiness, breathing difficulties (respiratory depression), coma and even death. Therefore, administering opioids with Brotizolam Teva should only be considered when there are no other treatment options. If the doctor instructs you to take Brotizolam Teva with opioids, he may limit the dosage and duration of treatment. Tell the doctor if you are taking medicines that contain opioids and adhere to the doctor's recommendations. If you notice any of the symptoms, refer to the doctor immediately.
- Strong pain relievers from the opioid group – concomitant use with Brotizolam Teva may increase the euphoria sensation and speed up the dependence.
- Muscle relaxants – in combination with Brotizolam Teva, there may be an increase in the muscle relaxing effect.
- Medicines for treatment of diabetes and high blood pressure, medicines for treatment of heart problems (such as digoxin), hormones – be cautious when using these medicines in combination with Brotizolam Teva, as there may be a mutual effect.
- The following medicines may cause an increase in the effect of Brotizolam Teva: antifungals from the azole group (such as itraconazole, ketoconazole), macrolide antibiotics (such as clarithromycin, erythromycin), protease inhibitors (such as indinavir, nelfinavir, ritonavir), cimetidine, astemizole, immunosuppressants (such as cyclosporine, sirolimus, tacrolimus), calcium channel blockers, antimalarial medicines such as mefloquine and halofantrine, midazolam, pimozide, sildenafil, cholesterol-lowering medicines of the statin group (such as atorvastatin, lovastatin, simvastatin), steroids (such as ethinyl estradiol), tamoxifen, terfenadine.
- The following medicines may cause a decrease in the effect of Brotizolam Teva: carbamazepine, efavirenz, St. John's Wort (hypericum), nevirapine, phenobarbital, phenytoin, primidone, rifabutin, rifampicin.

Use of the medicine and food
- The medicine should be taken on an empty stomach.
- You should not drink grapefruit juice during treatment.

Use of the medicine and alcohol consumption
Do not drink wine or alcoholic beverages during treatment with this medicine. Using alcohol during treatment with Brotizolam Teva may cause, among other things, sedation, sleepiness and impaired concentration.
Pregnancy, breastfeeding and fertility
Do not use this medicine when you are pregnant or breastfeeding.
Infants born to mothers who have taken benzodiazepines for a prolonged period during pregnancy may develop physical dependence. These children have shown withdrawal symptoms in the postpartum period. In addition, at high dosages in the advanced stages of pregnancy and close to birth, respiratory depression may occur in newborns. There is a low risk of impaired fetal development when using benzodiazepines during the early stages of pregnancy.
If you are pregnant, planning to become pregnant, or suspect you are pregnant, refer to the doctor.
There is no clinical data available on the effect of the medicine on fertility.
Use in children and adolescents
This medicine is not intended for children and adolescents under 18 years of age (efficacy and safety have not been studied in this population group).
The use in the elderly, debilitated patients, patients with impaired liver function or patients with respiratory insufficiency
This group may be more sensitive to the effects of the medicine and therefore it should be used with caution and in a reduced dosage. The effects of the medicine, especially in the elderly, include an increased risk of falls due to muscle relaxation (see "Introduction").
Driving and operating machinery

This medicine may affect reactivity, even when used according to the doctor's instructions, thereby impairing the ability to drive and operate machinery. Using this medicine may impair alertness, the ability to concentrate and muscle function (especially when the duration of sleep is insufficient or in combination with medicines that depress the central nervous system or in combination with alcohol). If you experience effects such as those listed above, do not drive or operate machinery. In any case, caution should be exercised when driving a vehicle, operating dangerous machinery and during any activity that requires alertness.

Important information about some of the ingredients of the medicine
Brotizolam Teva contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, talk to your doctor before taking the medicine.
This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?
Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
The dosage and treatment regimen will be determined only by the doctor.
The generally accepted dosage is:
Half a tablet to one tablet (according to the doctor's decision), before bedtime.
Do no exceed the recommended dose under any circumstances.
There is no information regarding crushing or chewing the tablets. Swallow the medicine with water.
The tablet can be halved on the marked score line.
The medicine is not intended for sublingual administration.
Make sure to get at least 7 hours of sleep after taking the medicine, in order to function properly after waking up (see also the section "Driving and operating machinery").
If you accidentally took a higher dosage
If you took an overdose or if a child accidentally swallowed this medicine, refer immediately to a hospital emergency room and take the package of the medicine with you.
Overdose symptoms may include drowsiness, confusion, tiredness. In severe cases there may be impaired coordination, a decrease in muscle tension, hypotension, respiratory depression, coma (rare) and death (very rare).
If you forgot to take this medicine at the appointed time, take the next dose as usual. There is no need to "compensate" for a forgotten dose and you should never take two doses together. If you accidentally took a double dose, refer to the doctor.
If you stop taking the medicine
Even if there is an improvement in your condition, do not discontinue treatment with the medicine abruptly without consulting the doctor. This instruction is especially important for a medicine like Brotizolam Teva (see "Introduction").
- Sometimes, after discontinuing the medicine, initially there may be a recurrence or worsening of the sleeping problems and in addition, in rare cases, restlessness, changes in mood, anxiety and stress. The risk for this is higher with abrupt discontinuation of treatment or abrupt dosage reduction.
- There may also be withdrawal symptoms after sudden discontinuation of the medicine (especially if dependence on the medicine has developed) such as: headaches, muscle pain, extreme anxiety, stress, sleeping problems, restlessness, confusion, nervousness. In severe cases, there may be misconception of reality, personality changes, loss of sensation and tingling in the hands and legs, hypersensitivity to light, noise and touch; hallucinations, epileptic fits. These effects may also occur several days after discontinuing the medicine. Please consult the doctor if you experience those withdrawal symptoms.
  Therefore, the doctor will reduce the dosage of the medicine gradually at the end of the treatment. The gradual reduction will be individually adjusted to the patient as it depends on several factors (such as the duration of treatment and the daily dose). Please consult the doctor on how to reduce the dosage.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS
As with any medicine, using Brotizolam Teva may cause side effects in some users. If a side effect occurs or if the side effects do not go away or are bothersome or if they worsen, consult your doctor. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Refer to a doctor immediately if the following side effects occur:
Paradoxical reactions such as: restlessness, agitation, nervousness, rage, aggressiveness, increased insomnia, nightmares, hallucinations, psychoses, changes in behavioral patterns including inappropriate behavior, confusion and restlessness (delirium) (uncommon side effects). These reactions may occur during treatment with benzodiazepines, especially in the elderly.
Additional side effects:
Common side effects (occur in 1-10 users out of 100):
Headache, light-headedness, digestive disorders.
Uncommon side effects (occur in 1-10 users out of 1,000):
Nightmares, depression, changes in mood, anxiety, dependence on the medicine, emotional disorders, behavioral changes, agitation, changes in sexual drive, dizziness, sedation (tiredness), lack of coordination and impaired body movement coordination (ataxia), memory disorders, dementia, mental and psychomotor impairment, visual disturbances (such as double vision), liver disorders (including jaundice and changes in the values of liver function tests), dry mouth, skin reactions, muscle weakness, withdrawal symptoms and recurrence or worsening of sleep problems after discontinuing the medicine, drowsiness (during the day), nervousness, increased risk of accidents and falls.
Rare side effects (occur in 1-10 users out of 10,000):
Confusion, restlessness, decreased alertness and preparedness.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
- The following side effects may appear, especially in the beginning of the treatment: drowsiness on the following day, emotional numbness, decreased alertness and preparedness, confusion, tiredness, dizziness, headache, muscle weakness, lack of coordination and impaired body movement coordination (ataxia), visual disturbances (double vision). These symptoms usually decrease during the treatment.
- As a result of the muscle relaxing effect, caution is required, especially in the elderly (risk for falling).
- Cases of benzodiazepine abuse have been reported.
- Withdrawal symptoms – physical and psychological dependence may develop during treatment. Abrupt discontinuation of the treatment may cause certain symptoms (see "If you stop taking the medicine" in section 3).
- Depression that preceded treatment with Brotizolam Teva may be detected during treatment.

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

5. HOW TO STORE THE MEDICINE?
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 without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place, below 25°C.**

6. ADDITIONAL INFORMATION
In addition to the active ingredient the medicine also contains:
Lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, povidone, magnesium stearate.
What does the medicine look like and what are the contents of the package?
White to off-white round tablet, with a score line on one side.
The pack contains 10 or 20 tablets. Not all package sizes may actually be marketed.
Name and address of the manufacturer and license holder:
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.
This leaflet was revised in July 2023 in accordance with the Ministry of Health guidelines.
Registration number of the medicine in the national drug registry of the Ministry of Health: 119.95.30040

BROTIZOLAM TAB PL MW0723

teva