

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

This medicine is dispensed with a doctor's prescription only

Vaben® Tablets

Active ingredient:

Each tablet contains 10 mg oxazepam.

Inactive ingredients:

Each tablet contains 69 mg lactose. 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, because it contains important information for you.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

This medicine has been prescribed for treatment for you only. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours. Report to the doctor or pharmacist any side effect you experience following use of the medicine (see side effects details in section 4).

Introduction to a patient package insert for benzodiazepines

This medicine belongs to the benzodiazepine group which has special properties requiring great caution while using it.

Close medical monitoring is extremely important when taking this medicine.

Treatment with this medicine is intended for as short a time period as possible, do not use the medicine for more than 4 weeks.

Prolonged use without a break may cause a severe effect of dependence, which will make it difficult for the patient to stop taking the medicine. The risk of developing dependence increases with the dose and length of treatment period. The risk of developing dependence increases if you have had a history of alcohol or drug abuse.

Uncontrolled discontinuation of treatment may be accompanied by withdrawal symptoms, such as: tension, nervousness, confusion, tremor, insomnia, abdominal pains, vomiting, nausea, sweating, convulsions, spasms, cramps and muscle pains. See 'If you stop taking the medicine' in section 3.

Sometimes, prolonged use of the medicine may cause changes in behavioral patterns and disturbing thoughts.

Particularly 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.

<p>Taking this medicine concomitantly with medicines from the opioid group, other medicines that depress the central nervous system (including drugs) or alcohol, may cause a feeling of profound drowsiness, breathing difficulties (respiratory depression), coma and death.</p>
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1. What is the medicine intended for?

The medicine is intended for calming in situations of stress and anxiety.

Therapeutic group: benzodiazepines.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, to other benzodiazepines, or to any of the additional ingredients the medicine contains (for the list of the additional ingredients, see section 6).
- You suffer from breathlessness or breathing difficulties.
- You suffer from acute pulmonary insufficiency, respiratory depression, sleep apnea (breathing pauses during sleep).
- You suffer from certain mental illnesses (e.g. psychoses, phobias or obsessions).
- You suffer from myasthenia gravis (severe muscular weakness).
- You suffer from severe liver disorders (e.g. severe liver failure).

Special warnings regarding the use of the medicine:

Before the treatment with Vaben, tell the doctor if:

- You suffer from **depression** (with or without anxiety).
- You suffer or have suffered in the past from **alcoholism** or **abuse of drugs or medicines**.
- You have **problems in the lungs, liver or kidneys**.
- You suffer or have suffered in the past from **mental illnesses** such as personality disorders.
- You have **porphyria** (a hereditary illness which may cause skin reactions such as blisters; abdominal pains and/or brain and nervous system disorders).
- You suffer from narrow angle **glaucoma**.
- You suffer from **low blood pressure**.

Additional warnings:

- **Dependence**: when taking the medicine there is a risk of developing dependence. The risk of developing dependence on the medicine increases when taking high doses and in prolonged treatment. In addition, the risk of developing dependence is higher in patients with a history of alcoholism or abuse of drugs or medicines.
- **Tolerance**: if after a few weeks of treatment, you feel that the medicine is not working as well as at the beginning of treatment, refer to the doctor.
- **Withdrawal**: discontinuation of the medicine should be done gradually. Withdrawal symptoms might occur, even when the recommended dosage was taken for short time periods. See the 'If you stop taking the medicine' section.
- The medicine may cause muscle relaxation and therefore caution should be exercised when taking it, since you may be at a greater risk of falling. Caution should be exercised especially when getting up at night.

Children and adolescents: this medicine is not recommended for children.

Use in the elderly: this group may be more sensitive to the effects of the medicine.

Drug interactions: (see also boxed warning at the beginning of the leaflet).

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):

- Medicines which affect the central nervous system, e.g. sedatives, sleeping medicines, antidepressants or antipsychotic medicines to treat mental problems; anesthetics, some antihistamines with a sedative effect (to treat allergies) such as chlorphenamine; lofexidine (for relief of symptoms accompanying opioid withdrawal); nabilone, alpha blockers, moxonidine; muscle relaxants (e.g. baclofen, tizanidine); probenecid (to treat gout): taking these medicines concomitantly with Vaben could cause increased sleepiness.
- Opioids (used as strong painkillers, medicines for withdrawal therapy, or sometimes as ingredients in cough suppressant medicines): taking concomitantly with Vaben may increase the risk of developing dependence (addiction) on these medicines and/or cause increased sleepiness. Concomitant use also increases the risk of breathing difficulties (respiratory depression), coma and threat to life. Therefore, concomitant use of Vaben with these medicines should only be considered when no other treatment options are available. However, if the doctor prescribes these medicines together, the dose and duration of the concomitant treatment will be limited by the doctor. Inform the doctor about any opioid medicine you are taking and follow the doctor's instructions precisely. It is recommended to inform friends and relatives of the symptoms detailed above. Refer to the doctor if these symptoms appear.
- Medicines to treat epilepsy, such as hydantoins and particularly phenytoin, or barbiturates: concomitant use with Vaben may increase the risk of side effects.
- Estrogen-containing contraceptives may reduce the effectiveness of Vaben.
- Rifampicin (antibiotic) - may cause Vaben to be eliminated from the body more quickly.
- Antiviral medicines (e.g. zidovudine, ritonavir).
- Medicines to lower high blood pressure.
- Medicines which inhibit liver enzymes (increase the effect of Vaben).
- Levodopa (and dopaminergic medicines) to treat Parkinson's disease: Vaben may cause reduced efficacy of levodopa.

Use of the medicine and alcohol consumption: do not drink alcohol (wine or alcoholic beverages) during the treatment period with this medicine.

Alcohol may increase the sedative effect of Vaben and make you very sleepy.

Pregnancy and breastfeeding:

Do not use the medicine if you are pregnant, think you are pregnant or are planning a pregnancy, or are breastfeeding.

- If the medicine is taken on a doctor's instruction towards the end of pregnancy or during labor, it may harm the baby. The baby may suffer from low body temperature, listlessness and breathing difficulties.
- If the medicine is taken regularly during late stages of pregnancy, the baby may develop withdrawal symptoms (including, amongst others, hypoactivity, feeding problems, sleep apnea, impaired metabolic reaction to cold. See also withdrawal symptoms in the 'If you stop taking the medicine' section).

Driving and use of machinery:

Vaben may affect how the muscles work, and/or make you feel dizzy, sleepy or forgetful. The medicine may also impair alertness (especially if you do not have enough (uninterrupted) sleep or in combination with alcohol). If you feel effects such as detailed above, **do not drive** or operate machinery. Do not drive until you know how the medicine affects you.

Important information about some of the medicine's ingredients:

The tablets contain 69 mg lactose (a type of sugar). If you have intolerance to certain sugars, inform the doctor before taking this medicine (see section 6).

3. How to use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The standard dosage is usually: the dosage, duration and manner of treatment will be determined by the doctor only.

You should make sure to have at least 7-8 hours of uninterrupted sleep.

- **The elderly and patients sensitive to medicines from the benzodiazepine group:** the doctor may recommend a reduced dosage.
- **Patients with liver or kidney problems:** the doctor may recommend a reduced dosage.

Swallow the medicine with water.

Do not exceed the recommended dose.

Adhere to the treatment duration determined by the doctor. It may be dangerous to stop treatment without consulting the doctor. The treatment duration usually will not exceed 2-4 weeks, and will be discontinued gradually. Abrupt discontinuation may cause side effects (see the 'If you stop taking the medicine' section).

There is no information on crushing or chewing the tablets.

To make swallowing easier you can halve the tablet for immediate use, if necessary. Swallow the two halves together immediately after halving.

If you have accidentally taken a higher dosage: if you or any person have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Symptoms of an overdose may include: lack of coordination, sleepiness, confusion, tiredness, apathy, rapid eye movements, speech problems. In severe cases (extreme overdose) low blood pressure, breathing difficulties, coma (loss of consciousness) may occur.

If you forgot to take the medicine at the set time, take a dose as soon as you remember and then continue with the set times. Do not take a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine:

This medicine should not be stopped suddenly; keep taking the medicine until the doctor tells you how to reduce the dose gradually.

If you stop taking the tablets suddenly you may experience the following withdrawal symptoms:

- Depression
- Nervousness
- Difficulty in sleeping
- Irritability
- Sweating
- Upset stomach/diarrhea
- Or the symptoms, for which you are being treated with the medicine, may return or worsen.

You may also experience mood changes, anxiety, agitation and changes in sleep patterns.

These effects may occur even after taking low dosages for a short time period.

If you stop taking these tablets suddenly after being treated with high dosages of Vaben, you may experience confusion, hallucinations, shaking, a faster heartbeat or seizures. The withdrawal symptoms may also cause abnormal behavior including aggressive outbursts, excitement or depression with suicidal thoughts or actions.

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 Vaben may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if the following side effects appear, the doctor may need to stop the treatment gradually:

- Restlessness, agitation, irritability, aggressiveness, delusion, rage, nightmares, hallucinations (seeing or hearing things that are not real), psychoses, changes in the regular behavior patterns (inappropriate behavior), depression with suicidal thoughts.
- If you notice symptoms that might indicate blood cell changes, e.g. increased bruising, nosebleed, sore throat, infections, excessive tiredness, breathlessness on exertion, or abnormal paleness; in this case, the doctor may recommend blood tests.

Additional side effects:

- Drowsiness and lightheadedness. These effects may occur during the first few days of treatment.
- Allergic reactions, such as skin rashes, itchiness.
- Dizziness, fainting, loss of coordination; 'spinning' sensation (vertigo) or headache, drowsiness, tiredness.
- Decrease in alertness and preparedness, confusion and disorientation, dreams, excitement, apathy, impaired speech including slurring, loss of memory, impaired coordination of body movements, difficulty or inability to control muscles, changes in perception, falls (increased risk of falling).
- Reduction in white blood cells, changes in the sex drive, visual disturbances such as blurred or double vision, low blood pressure, muscle weakness, tremor, fever.
- Digestive system problems, abdominal cramps or pains, nausea, changes in saliva.
- Increase in liver enzymes seen in tests, jaundice (yellowing of the skin or whites of the eyes), difficulty passing urine (urinary retention), water retention (edema), lack of control over urination or defecation.
- Withdrawal symptoms - see the 'If you stop taking the medicine' section.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult 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 babies, 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.

6. Additional information

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

Lactose, corn starch, povidone K25, magnesium stearate.

What does the medicine look like and what does the package contain?

Round white tablets imprinted with a V, packed in blisters, in boxes of 30 tablets.

Manufacturer and Registration Holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301, Israel

Medicine registration number in the National Medicines Registry of the Ministry of Health: 022-06-21031

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