

Vaben tablets

Active ingredient:

Each tablet contains 10 mg Oxazepam.

For the list of other ingredients, see section 6.

See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the 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 treatment for you. Do not pass it on to others. It may harm them, even if you think their medical condition is similar to yours.

Introduction to the patient leaflet 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.

When taking this medicine, be sure to contact the doctor after 2 to 4 weeks, since the treatment is intended for short periods only.

Prolonged use of the 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.

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.

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.

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 other ingredients the medicine contains (for a list of the other ingredients, see section 6).
- You suffer from breathlessness or breathing difficulties.
- You suffer from acute pulmonary insufficiency, respiratory depression, sleep apnea (stop breathing while sleeping).
- 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 this medicine:

Before the treatment with Vaben, tell your 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 this 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 when you started treatment, contact your doctor.
- **Withdrawal**: discontinuation of the medicine should be done gradually. Withdrawal symptoms might occur, even when the recommended dosage was taken for short periods of time. See the 'If you stop taking the medicine' section.

- The medicine may cause muscle relaxation and therefore caution is advised 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 warning in the box at the beginning of the leaflet).

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 indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines, please check with your doctor or pharmacist):

- Medicines which affect the central nervous system, e.g. sedatives, sleeping pills, antidepressants or antipsychotic medicines to treat mental problems; anesthetics, some antihistamines with sedative effect (to treat allergies) such as chlorphenamine; lofexidine (for relief of symptoms accompanying stopping opioid); 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 medicines): Taking these medicines concomitantly with Vaben can increase the risk of developing dependence (addiction) on these medicines and/or cause increased drowsiness. Concomitant use also increases the risk of breathing difficulties (respiratory depression), coma and may be life threatening. Therefore, concomitant use of Vaben with these medicines should only be considered when no other treatment options are

available. However, if your doctor does prescribe these medicines together, the dose and duration of the concomitant treatment will be limited by the doctor. Tell your doctor about any opioid medicine you are taking and follow your doctor's instructions precisely. It is recommended to inform friends and relatives of the symptoms detailed above. Contact your doctor if you experience any of these symptoms.

- Medicines for epilepsy, such as hydantoins and particularly phenytoin, or barbiturates: concomitant use with Vaben may increase the risk of side effects.
- Estrogen-containing contraceptives can reduce the effectiveness of Vaben.
- Rifampicin (an antibiotic) - can 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 can cause reduced efficacy of levodopa.

Use of the medicine and alcohol consumption: do not drink alcohol (wine or alcoholic beverages) during the treatment 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, planning a pregnancy or are breastfeeding.

- If the medicine is taken late in a pregnancy or during labor, the baby may have low body temperature, floppiness and breathing difficulties.
- If you take the medicine regularly during late stages of pregnancy, your baby may develop withdrawal symptoms (including amongst other hypoactivity, feeding problems, sleep apnea, impaired metabolic reaction to cold. See also withdrawal symptoms in the 'If you stop taking the medicine' section).

Consult your doctor or pharmacist before taking any medicine.

Driving and use of machinery:

Vaben may affect how your muscles work, and/or make you feel dizzy, sleepy or forgetful. The medicine may also impair your alertness (especially if you do not have enough uninterrupted sleep or in combination with alcohol). If you feel any effects such as listed 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 lactose (a type of sugar). If you have intolerance to some sugars, inform your doctor before taking this medicine (see section 6).

3. How to use this medicine?

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

The standard dosage is usually: the dosage and treatment regimen will be determined by the doctor only.

The duration of the treatment will be determined by the doctor.

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

- **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.

Strictly observe the treatment duration determined by your doctor. It may be dangerous to stop treatment without consulting your 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 the tablet.

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 determined set times. Do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by your doctor.

If you stop taking the medicine: even if your condition improves, do not stop the treatment with the medicine without consulting your doctor.

- Treatment with the medicine will be discontinued according to your doctor's instruction, who may recommend gradual (not abrupt) withdrawal. Sudden discontinuation of the medicine may cause side effects (withdrawal symptoms) such as headaches, cramps or muscle pains, increased anxiety, tension, abdominal cramps, insomnia, vomiting, confusion, ringing in the ears, involuntary movements, feeling of 'pins and needles', depression, sweating. If you have been on a high dose treatment, with sudden discontinuation of the medicine you may also experience convulsions, abnormal behavior, delusions (feeling the world around you is not real), feeling your mind is separated from your body, hypersensitivity to light, noise and contact, hearing problems, numbness, hallucinations.
- Sometimes after discontinuation of the medicine, there may be a return or worsening of the symptoms you are being treated for with the medicine. The risk of this is greater if the treatment is not discontinued gradually. You may also experience mood changes, anxiety, restlessness, changes in sleep patterns.

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 your doctor or pharmacist.

4. Side effects

Like 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.

Contact your doctor immediately, if the following side effects appear:

- Restlessness, agitation, irritability, aggressiveness, delusion, rage, nightmares, hallucinations (seeing or hearing things that are not real), psychoses, changes in 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 of the skin; 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, itching.
- 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 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), incontinence (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 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 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.

6. Additional information

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

Lactose, corn starch, povidone K25, magnesium stearate.

Each tablet contains about 69 mg lactose.

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

Medicine registration number in the National Medicines Registry of the Ministry of Health: 0220621031

The format of this leaflet was determined by the Ministry of Health, who checked and approved its content in January 2012, and it was updated according to the Ministry of Health guidelines in May 2020.
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