

Patient Leaflet in Accordance with the Pharmacist' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Jorveza[®] 1 mg Orodispersible tablets

Active ingredient:

Each orodispersible tablet contains: 1 mg budesonide.

For a list of the 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 the doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

The medicine is intended for the treatment of eosinophilic esophagitis in adults.

Therapeutic group: steroidal (corticosteroidal) anti-inflammatory medicine with local activity.

2. Before using the medicine

Do not use the medicine if:

You are sensitive (allergic) to the active ingredient (budesonide) or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).

Special warnings regarding the use of this medicine:

Before starting the treatment with the medicine, tell your doctor if:

- You have tuberculosis, high blood pressure, weak bones (osteoporosis).
- You or someone in your family has diabetes.
- You have ulcers in the stomach or in the intestine.
- You have increased pressure in your eye (which can cause glaucoma), glaucoma, eye problems such as clouding of the lens (cataract), or if someone in your family has glaucoma.
- You have liver or kidney disease.

If you have any of the conditions mentioned above, you may be at an increased risk of side effects. Your doctor will decide whether the medicine is suitable for you and whether appropriate monitoring is necessary.

Additional warnings:

- If you develop swelling of the face, particularly around the mouth (lips, tongue and/or throat), the eyelids and/or difficulties breathing or swallowing, stop taking Jorveza and refer to the doctor immediately. These symptoms may be a sign of an allergic reaction, which may also include rash and itching.
- The medicine may cause side effects, typical of steroidal medicines, in all parts of the body (systemic side effects). These side effects may occur particularly with a high dosage and/or with long-term use and they also depend on the use of other steroidal medicines and your sensitivity to the treatment. See section 4 'Side effects'.
- Contact the doctor if you get blurred vision or have other problems with your vision.
- Inform the doctor that you are taking the medicine before carrying out tests, since the medicine might affect the results of certain tests (for instance adrenal function tests - ACTH stimulation test).

Since during the treatment with the medicine your immune system may be weakened, take the following precautions:

- Contact the doctor if fungal infections develop in the mouth, throat and/or gullet, or if you think any infection develops during treatment with this medicine. Symptoms of fungal infection can include white spots in the mouth and throat and difficulty in swallowing. The symptoms of some infections can be atypical, so if you suspect any infection contact the doctor.
- Avoid being exposed to patients with shingles (herpes zoster), measles or chickenpox (especially if you have never contracted these diseases in the past). The effects of these diseases can be much more severe during treatment with this medicine. In case you have been exposed to these diseases, refer to the doctor straight away. Inform the doctor of your vaccination status.
- Tell the doctor if you have never had measles and/or if and when you were vaccinated against measles.
- If you need any vaccination please consult with the doctor before getting the vaccination.
- If you are due to have an operation please tell the doctor that you are taking this medicine.

Children and adolescents:

The medicine should not be used in children and adolescents under 18 years of age. The use in this age group has not been studied.

Drug interactions:

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Some of the following medicines may increase the effects of Jorveza and the doctor may decide to monitor you carefully during the time you are taking these medicines.

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 check with the doctor or pharmacist):

- Ketoconazole or itraconazole (for the treatment of fungal infections).
- Clarithromycin (an antibiotic).
- Ritonavir, cobicistat (for the treatment of HIV infections).
- Estrogens (used for hormone replacement therapy or in contraceptives).
- Cardiac glycosides (such as digoxin, for the treatment of heart problems).
- Diuretics.

Use of the medicine and food:

- Do not eat or drink at least half an hour after taking this medicine (see 'Manner of use' in section 3).
- Take this medicine after eating (see 'Manner of use' in section 3).
- Avoid grapefruits during the treatment period with this medicine, since the medicine's side effects may worsen.

Pregnancy and breastfeeding:

Do not use the medicine without consulting a doctor if you are pregnant, think you are pregnant, are planning a pregnancy, or are breastfeeding.

- Do not use the medicine during pregnancy, unless explicitly instructed by your doctor.
- The medicine passes into the breastmilk (in small quantities). Do not use the medicine while breastfeeding, unless otherwise instructed by your doctor.

Driving and use of machinery:

The use of the medicine is not expected to affect your ability to drive or operate machinery.

Important information about some of the medicine's ingredients:

Each tablet contains 26 mg sodium.

3. How to use the medicine?

Always use according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment.

The dosage and the manner of treatment will be determined by the doctor only.

The standard dosage of Jorveza orodispersible tablets is usually:

One tablet in the morning and one in the evening after a meal.

Do not exceed the recommended dose.

Manner of use:

- Use the medicine immediately once removed from the blister pack.
- Place the tablet on the tip of your tongue and close your mouth. Press the tablet gently against the roof of your mouth with your tongue until it has dissolved completely (this usually takes at least two minutes) and slowly swallow the dissolved material.
- Do not drink or eat with the dissolving tablet.
- Do not chew or swallow the tablet as long as it has not dissolved in your mouth.
- Do not eat, drink, brush your teeth or rinse your mouth for at least 30 minutes after you have taken Jorveza. Do not use any chewable tablets, oral solutions or sprays, for at least 30 minutes before taking Jorveza and for at least 30 minutes after taking it. Strict adherence to the manner of use will ensure that the medicine works properly.

Patients with liver or kidney problems: tell the doctor if you suffer from liver or kidney problems.

- If you have kidney problems, the doctor will decide if Jorveza is suitable for you. If the kidney problems are severe, do not take Jorveza.
- If you have liver problems, do not take Jorveza.

Duration of treatment:

The treatment should last about 6 to 12 weeks. If the symptoms do not improve in the first 6 weeks of treatment, you may need to take the medicine for up to 6 more weeks. The doctor will decide for how long you are to continue the treatment, depending on your condition and your response to the treatment.

If you have accidentally taken a higher dosage: if you have taken too many tablets, take the next dose as instructed by the doctor. Consult a doctor if you are not sure what to do. Bring the medicine package with you.

If you forgot to take the medicine: if you missed a dose, take the next dose as usual. Do not take a double dose to compensate for the forgotten dose.

Continue the treatment as recommended by the doctor. Even if your state of health improves, do not stop the treatment with this medicine without consulting the doctor. It is important not to stop treatment without consulting the doctor.

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 Jorveza 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.

Stop the treatment and refer to the doctor immediately if allergic reactions occur that may cause swelling of the face, especially of eyelids, lips, tongue or throat (angioedema). See also 'Additional Warnings' in section 2.

Very common side effects (appear in more than 1 user out of 10):

- Fungal infections in the gullet (which can cause pain or discomfort when swallowing)

Common side effects (appear in 1-10 users out of 100):

- Headache
- Fungal infections in the mouth and throat (symptoms may include white spots)
- Heartburn
- Indigestion
- Nausea
- Tingling or numbness in the mouth
- Tiredness
- Decreased amount of the hormone cortisol in the blood

Uncommon side effects (appear in 1-10 users out of 1,000):

- Difficulty sleeping
- Anxiety
- Dizziness
- Taste disorders
- Dry eyes
- High blood pressure
- Cough, dry throat
- Abdominal pain, upper abdominal pain
- Difficulty swallowing
- Inflammation of the stomach, ulcers in the stomach
- Burning tongue, swelling of lips, dry mouth
- Rash, itchy rash (urticaria)
- Sensation of foreign body
- Pain in mouth or throat
- Allergic reactions that may cause swelling of the face, especially of eyelids, lips, tongue or throat (angioedema)

The following side effects are typical for corticosteroidal medicines similar to Jorveza, and can therefore also occur when using this medicine. The frequency of these side effects is unknown:

- Increased risk of infections
- Cushing's syndrome, which is associated with excess corticosteroids and causes swelling in the face (round face), weight gain, high levels of blood sugar, accumulation of fluid in the tissues (edema, manifested for instance by swelling of the legs), low potassium level in the blood (hypokalemia); irregular periods in women, unwanted body hair in women, impotence; stretch marks (streaks) on the skin, acne
- Adrenal suppression
- Slowed growth in children
- Mood changes, such as depression, irritability/nervousness or euphoria
- Restlessness with increased physical activity, aggression
- Increased pressure in the brain (pseudotumor cerebri), possibly with increased pressure in the eye in adolescents
- Blurred vision and/or other eye and vision problems. In this case refer to the doctor
- Increased risk of blood clot formation, inflammation of the blood vessels (which can also happen when the medicine is stopped after prolonged use)

- Glaucoma (increased pressure in the eye), cataract (clouding of the eye lens)
- Constipation, ulcers in the small intestine
- Inflammation of the pancreas (causes severe stomach and back pain)
- Rash, red spots from bleeding in the skin, delayed wound healing, skin reactions such as skin inflammation from contact (contact dermatitis), bruising
- Muscle and joint pain, muscle weakness, muscle twitching
- Atrophy and weakening of the bones (osteoporosis), bone damage due to poor blood circulation (osteonecrosis)
- Feeling ill and generally unwell

If a side effect appears, if one 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 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) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C, in the original package in order to protect against light and humidity.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Disodium hydrogen citrate, Sodium hydrogen carbonate, Monosodium citrate anhydrous, Mannitol, Macrogol 6000, Povidone K25, Sucralose, Magnesium stearate, Docusate sodium.

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

Round white tablets.

The tablets are in blister packs. The pack contains 30 or 90 tablets.

Not all pack sizes may be marketed.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Manufacturer: Dr. Falk Pharma GmbH, Freiburg, Germany

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163-16-36104

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