Patient Leaflet According to the Pharmacists' 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 your 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 (inflammation of the gullet) 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 or to any of the other ingredients the medicine contains (for a list of the other 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:

- The medicine may cause typical systemic steroidal side effects. These side effects may occur particularly if you take a high dosage of this medicine and/or over a prolonged period, and they also depend on the use of other steroidal medicines and your sensitivity to the treatment. See 'Side effects' section.
- Contact your doctor if you get blurred vision or have other problems with your vision.
- Tell your doctor that you are taking the medicine, before carrying out tests, since the medicine might affect the results of some tests (for instance adrenal function tests).

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

- Contact your 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 your 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, see your doctor straight away. Report your vaccination status to your doctor.
- Tell your 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 your doctor before getting the vaccination.
- If you are due to have an operation please tell your 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 nutrition supplements, inform your doctor or pharmacist. Some of the following medicines may increase the effects of Jorveza and your doctor may decide to monitor you more carefully during the time you are taking these medicines.
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):
- Ketoconazole or itraconazole (to treat fungal infections).
- Clarithromycin (an antibiotic).
- Ritonavir, cobicistat (to treat HIV infections).
- Estrogens (used for hormone replacement therapy or contraception).
- Cardiac glycosides (such as digoxin, to treat heart problems).
- Diuretics.

Use of this 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, planning a pregnancy, or are breastfeeding.
- Avoid using the medicine during pregnancy, unless explicitly instructed so 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 this 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 this medicine?
Always use according to the doctor's instructions. You should check with your 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 meals.
Do not exceed the recommended dosage.

Manner of use:

- 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 about 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 your doctor if you suffer from liver or kidney problems.

- If you have kidney problems, your 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:
Your treatment should last about 6 to 12 weeks. If your symptoms do not improve in the first 6 weeks of treatment, you may need to take this medicine for up to 6 more weeks. Your 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 your next dose as instructed by your 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 make up for a forgotten dose.

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

4. Side effects

Like 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.

Very common side effects (appear in more than one user out of ten):

- 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).
- High blood pressure
- Pain in the upper part of the abdomen.
- Heartburn.
- Swelling of the lips.
- Nausea.
- Tingling or numbness in the mouth.

- Tiredness.
- Decreased amounts of the hormone cortisol in the blood.

The following side effects are typical for corticosteroids 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 known to be associated with too much corticosteroid and may cause swelling in the face (round face), weight gain, high levels of blood sugar, build-up of fluid in the tissues (edema, manifested for instance by swelling of the legs), low potassium level in the blood (hypokalemia); menstrual disorders in women, excess hair growth in women, impotence; red streaks on the skin (stretch marks), acne.
- Adrenal suppression.
- Slowed growth in children.
- Mood changes, such as depression, irritability/nervousness or euphoria.
- Restlessness with increased physical activity, anxiety, 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.
- Increased risk of blood clots 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).
- Digestive system disorders, indigestion, constipation, ulcers in the stomach and/or 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.
- 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 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 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, in the original package in order to protect from light and moisture.

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 packed in blisters. The package 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
Medicine registration number in the National Medicines Registry of the Ministry of Health:
163-16-36104

This leaflet was checked and approved by the Ministry of Health in December 2019.

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