Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Jorveza® 0.5 mg
Jorveza® 1 mg
Orodispersible tablets

Active ingredient:

Each Jorveza 0.5 mg orodispersible tablet contains: 0.5 mg budesonide.

Each Jorveza 1 mg orodispersible tablet contains: 1 mg budesonide.

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 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 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 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, 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. See section 4 'Side effects'.
- The medicine may cause side effects that are typical for steroidal medicines, in all parts of the body (systemic side effects). These side effects may occur particularly with a high dosage and/or over a prolonged period 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 experience blurred vision or other vision problems.

- 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 weaken, take the following precautions:

- Contact your doctor if fungal infections develop in the mouth, throat and/or gullet, or if you think any infection developed during treatment with the 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 or less pronounced, so if you suspect any infection refer to the doctor.
- Avoid exposure to patients with shingles (herpes zoster), measles or chickenpox (especially if you have not contracted these diseases in the past). The effects of these diseases can be much more severe during treatment with this medicine. If 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 any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Some of the following medicines may increase the effects of Jorveza, and the doctor may decide to monitor you more 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 your doctor or pharmacist):

- Ketoconazole, itraconazole (to treat fungal infections).
- Clarithromycin (an antibiotic).
- Ritonavir, cobicistat (to treat HIV infection).
- Estrogens (used for hormone replacement therapy or contraceptives).
- 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 the medicine (see 'Manner of use' in section 3).
- Use the medicine after a meal (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, breastfeeding and fertility:
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 so by the doctor.
- The medicine passes into the breastmilk. Do not use the medicine during the breastfeeding period, unless otherwise instructed by the doctor since the nursing infant may suffer minor effects.
- There is no information on the effect of the medicine on fertility.

Driving and use of machinery:

The use of the medicine is not expected to affect or may have a negligible effect on your ability to drive or operate machinery.

Important information about some of the medicine's ingredients:
Jorveza 0.5 mg and Jorveza 1 mg contain 26 mg sodium per tablet.
The sodium content in a daily dose of two Jorveza 1 mg tablets or of two Jorveza 0.5 mg tablets is 52 mg. This amount constitutes 2.6% of the recommended maximum consumption dose for adults, which is 2 g.

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 for acute treatment is usually:
One Jorveza 1 mg tablet in the morning and one Jorveza 1 mg tablet in the evening, after a meal.

The standard dosage in maintenance treatment is usually:
One Jorveza 0.5 mg tablet in the morning and one Jorveza 0.5 mg tablet in the evening or one Jorveza 1 mg tablet in the morning and one Jorveza 1 mg tablet in the evening, after a meal. The dosage will be determined by the doctor according to your response to the treatment.

Do not exceed the recommended dose.

How to take the medicine:
- 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 disintegrated/dissolved (this process usually takes at least about two minutes but can take up to 20 minutes), and slowly swallow with your saliva while the tablet is disintegrating. The disintegration of the tablet in your mouth starts after it comes into contact with the saliva.
- Do not drink or eat with the disintegrating tablet.
- Do not chew or swallow the tablet as long as it has not disintegrated in your mouth.
- Do not eat, drink, brush your teeth or rinse your mouth for at least 30 minutes after taking Jorveza. Do not use any chewable tablets, oral solutions or sprays, for at least 30 minutes before and at least 30 minutes after taking Jorveza. 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 use Jorveza.
- If you have liver problems, do not use Jorveza.

Duration of treatment:
The acute 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 a period of up to 6 more weeks, as decided by your doctor depending on your condition and your response to the treatment.

The duration of the maintenance treatment will be determined by the doctor, depending on your condition and your response to the treatment.

If you accidentally took a higher dosage: if you accidentally took more tablets than you should, take the next dose as instructed by the doctor. Refer to the doctor or pharmacist 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 at the scheduled time and consult the doctor. Do not take a double dose to make up for the forgotten dose.

If you stop taking the medicine:
Adhere to the treatment as recommended by your 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 <u>each time</u> 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 you notice one of the following side effects:
- Swelling of the face, especially of the eyelids, lips, tongue or throat (angioedema). These side effects may indicate an allergic reaction (uncommon). 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 (can cause pain or discomfort when swallowing).
- Fungal infections in the mouth and throat (symptoms may include white spots).

Common side effects (appear in 1-10 users out of 100):
- Headache.
- Heartburn.
- Indigestion.
- Nausea.
- Tingling or numbness in the mouth, dry mouth.
- Taste disorders, burning tongue.
- Upper abdominal pain.
- Tiredness.
- Decreased amount of the hormone cortisol in the blood.
- Dry eyes.
- Sleep disorder.
- Problems with tongue.
- Cold sores (oral herpes).

Uncommon side effects (appear in 1-10 users out of 1,000):
- Anxiety, agitation.
- Dizziness.
- High blood pressure.
- Cough, dry throat, sore throat, common cold.
- Abdominal pain, abdominal bloating.
- Swallowing difficulties.
- Inflammation of the stomach, ulcers in the stomach.

- Swelling of the lips.
- Rash, itchy rash (urticaria).
- Sensation of foreign body.
- Pain in mouth or throat (oropharyngeal pain).
- Painful gums.
- Decreased level of osteocalcin.
- Weight gain.
- Allergic reactions that may cause swelling of the face, especially of the eyelids, lips, tongue or throat (angioedema). See beginning of section 4 'Side effects'.

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 an excess of corticosteroids and may cause swelling in the face (round face), weight gain, high levels of blood sugar, accumulation of fluid in the tissues (edemas, manifested for instance by swelling of the legs), low blood potassium level (hypokalemia); menstrual disorders 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 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 clots, inflammation of the blood vessels (which can also happen when the medicine is stopped after prolonged use).
- Glaucoma (increase in pressure in the eye), cataract (clouding of the eye lens).
- Constipation, ulcers in the small intestine.
- Inflammation of the pancreas (causes severe abdominal and back pain).
- Rash, red spots from bleeding in the skin, delay in 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 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, in the original package in order to protect from light and moisture.

6. Additional information

In addition to the active ingredient Jorveza 0.5 mg and Jorveza 1 mg tablets also contain per tablet:

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 packaged in blisters.
Jorveza 0.5 mg: a pack contains 20, 30, 60, 90, 100, or 200 tablets.
Jorveza 1 mg: a 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

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

Jorveza 0.5 mg: 172-53-36975-99
Jorveza 1 mg: 163-16-36104-00

Revised in April 2023 in accordance with the Ministry of Health guidelines.