Package leaflet: Information for the patient

Jorveza 1 mg orodispersible tablets
budesonide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet

1. What Jorveza is and what it is used for
2. What you need to know before you take Jorveza
3. How to take Jorveza
4. Possible side effects
5. How to store Jorveza
6. Contents of the pack and other information

1. What Jorveza is and what it is used for

Jorveza contains the active substance budesonide, a corticosteroid medicine that reduces inflammation.

It is used in adults (older than 18 years of age) to treat eosinophilic oesophagitis, which is an inflammatory condition of the gullet (food pipe) that causes problems with swallowing food.

2. What you need to know before you take Jorveza

Do not take Jorveza
- if you are allergic to budesonide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Jorveza if you have:
- tuberculosis
- high blood pressure
- diabetes, or if somebody in your family has diabetes
- weakening of the bones (osteoporosis)
- ulcers in the stomach or first part of the small intestine (peptic ulcer)
- increased pressure in your eye (which can cause glaucoma) or eye problems such as clouding of the lens (cataracts) or if somebody in your family has glaucoma
- liver disease.

If you have any of the conditions mentioned above you may be at increased risk of side effects. Your doctor will decide on the appropriate measures and if it is still all right for you to take this medicine.

Jorveza may cause typical side effects of corticosteroid medicines and may affect all parts of the body, particularly when you take this medicine at high doses and over a long time (see section 4).
Further precautions during treatment with Jorveza

- Contact your doctor if you get blurred vision or have other problems with your vision.

Take the following precautions during treatment with Jorveza because your immune system may be weakened:

- Tell your doctor if you get fungal infections in the mouth, throat and gullet or if you think you have any infection during treatment with this medicine. Symptoms of fungal infection can be white spots in the mouth and throat and difficulty in swallowing. The symptoms of some infections can be unusual or less noticeable.
- Keep away from people who have chickenpox or herpes zoster (shingles) if you have not had these infections. The effects of these illnesses can be much more severe during treatment with this medicine. If you do come into contact with chickenpox or shingles, see your doctor straight away. Please also report your vaccination status to your doctor.
- Tell your doctor if you have not yet had measles and/or if and when you have received your last vaccination for this disease.
- If you need to be vaccinated please speak to your doctor first.
- If you know that you are due to have an operation please tell your doctor that you are taking Jorveza.

Children and adolescents

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

Other medicines and Jorveza

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some of these medicines may increase the effects of Jorveza and your doctor may wish to monitor you carefully if you are taking these medicines.

In particular:

- ketoconazole or itraconazole (to treat fungal infections)
- clarithromycin, an antibiotic medicine used to treat infections
- ritonavir and cobicistat (to treat HIV infections)
- oestrogens (used for hormone replacement therapy or contraception)
- cardiac glycosides such as digoxin (medicines used to treat heart conditions)
- diuretics (to remove excess fluid from the body).

Jorveza could affect the results of adrenal function tests (ACTH stimulation test) ordered by your doctor or in hospital. Tell your doctors that you are taking Jorveza before you have any tests.

Jorveza with food and drink

You should not drink grapefruit juice whilst you are taking this medicine as this can worsen its side effects.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine during pregnancy without checking with your doctor first.

Do not take this medicine if you are breast-feeding unless you have checked with your doctor. Budesonide passes in small amounts into the breast milk. Your doctor will help you decide whether you should continue treatment and not breast-feed or if you should stop treatment over the period your baby is being breast-fed.

Driving and using machines

Jorveza is not expected to affect your ability to drive or use machines.
**Jorveza contains sodium**
This medicine contains 52 mg sodium (main component of cooking/table salt) per daily dose. This is equivalent to 2.6% of the recommended maximum daily dietary intake of sodium for an adult.

3. **How to take Jorveza**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is two orodispersible tablets (2 mg budesonide) per day. Take one orodispersible tablet in the morning and one orodispersible tablet in the evening.

**Method of administration**
Take the orodispersible tablet after a meal.

Place the orodispersible tablet on the tip of your tongue and close your mouth. Press it gently against the roof of your mouth with your tongue until it has dissolved completely (this usually takes about two minutes). Swallow the dissolved material with saliva little by little, as the orodispersible tablet breaks up.
Do NOT take any liquid with the orodispersible tablet.

Do not chew or swallow the undissolved orodispersible tablet.

Do not eat, drink, brush your teeth or rinse your mouth for at least 30 minutes after you have taken the orodispersible tablet. Do not use any oral solutions, sprays or chewable tablets for at least 30 minutes before or after administration of the orodispersible tablet. This will ensure that your medicine works properly.

**Kidney and liver problems**
If you have any problem with your kidney or liver, talk to your doctor. If you have a kidney problem, your doctor will decide if Jorveza is suitable for you. In case your kidney problems are severe, you should not take Jorveza. If you have any liver disease, you should not take Jorveza.

**Duration of treatment**
Your treatment should last about 6 to 12 weeks. In case your symptoms do not get better in the first 6 weeks of treatment, you may need to take this medicine for up to 6 more weeks.
Your doctor will decide how long you are to continue the treatment, depending on your condition and your response to the treatment.

**If you take more Jorveza than you should**
If you have taken too many orodispersible tablets on one occasion, take your next dose as prescribed. Do not take a smaller amount. Contact a doctor if you are in doubt. Take the carton and this leaflet with you if possible.

**If you forget to take Jorveza**
If you miss a dose, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Jorveza**
Speak to your doctor if you want to interrupt or end your treatment early. It is important that you do not stop taking your medicine without talking to your doctor. Keep taking your medicine until your doctor tells you to stop, even if you feel better.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported during the use of Jorveza:

**Very common: may affect more than 1 in 10 people**
- fungal infections in the gullet (which can cause pain or discomfort when swallowing)

**Common: may affect up to 1 in 10 people**
- headache
- fungal infections in the mouth and throat (symptoms can be white spots)
- high blood pressure
- pain in the upper part of your belly
- heartburn
- swelling of the lips
- feeling sick (nausea)
- tingling or numbness in your mouth
- tiredness
- decreased amount of the hormone cortisol in your blood.

The following side effects have been reported and are typical with medicines similar to Jorveza (corticosteroids), and can therefore also occur with this medicine. The frequency of these events is currently not known:
- increased risk of infection
- Cushing’s syndrome, which is associated with too much corticosteroid and causes roundness of the face, weight gain, high blood sugar, build-up of fluid in the tissues (e.g. swollen legs), reduced potassium level in the blood (hypokalaemia), irregular periods in women, unwanted body hair in women, impotence, stretch marks on the skin, acne.
- slowed growth in children
- mood changes, such as depression, irritability or euphoria
- restlessness with increased physical activity, anxiety, aggression
- increased pressure in the brain, possibly with increased pressure in the eye (swelling of the optic disk) in adolescents
- blurred vision
- increased risk of blood clots, inflammation of the blood vessels (which can happen when the medicine is stopped after long-term use)
- indigestion, dyspepsia, constipation, ulcers in the stomach or small intestine
- inflammation of the pancreas, which causes severe pain in the belly and back
- rash, red spots from bleeding in the skin, delayed wound healing, skin reactions such as contact dermatitis, bruising
- muscle and joint pain, muscle weakness, muscle twitching
- weakening of the bones (osteoporosis), bone damage due to poor circulation of blood (osteonecrosis)
- general feeling of being ill.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

**Ireland**
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Jorveza**

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton and blister after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package in order to protect from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. **Contents of the pack and other information**

**What Jorveza contains**

- The **active substance** is budesonide. Each orodispersible tablet contains 1 mg of budesonide.

- The **other ingredients** are disodium hydrogen citrate, docusate sodium, macrogol 6000, magnesium stearate, mannitol, anhydrous monosodium citrate, povidone K25, sodium hydrogen carbonate and sucralose (see also section 2, “Jorveza contains sodium”).

**What Jorveza looks like and contents of the pack**

The orodispersible tablets are white, round, biplane tablets.

Jorveza comes in blisters in packs with 20, 30, 60, 90 or 100 orodispersible tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Dr. Falk Pharma GmbH
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in May 2019.
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.