Package leaflet: Information for the patient
Jorveza 0.5 mg orodispersible tablets
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 in this leaflet

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.

If you develop swelling of your face, particularly around your mouth (lips, tongue or throat) and/or difficulties to breathe or swallow, stop taking Jorveza and contact your doctor immediately. These may be signs of an allergic reaction, which may also include rash and itching (see also section 4).

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.

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.

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 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 for treatment of acute episodes is two 1 mg orodispersible tablets (2 mg budesonide) per day. Take one 1 mg orodispersible tablet in the morning and one 1 mg orodispersible tablet in the evening.

The recommended dose for prevention of further episodes is two 0.5 mg orodispersible tablets (1 mg budesonide) per day or two 1 mg orodispersible tablets (2 mg budesonide) per day, depending on your body's response to the treatment. Take one orodispersible tablet in the morning and one orodispersible tablet in the evening.

Method of administration
Take the orodispersible tablet immediately once removed from the blister package.

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 disintegrated completely (this usually takes at least two minutes but may take up to 20 minutes). Swallow the disintegrated 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 undisintegrated 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
Initially, your treatment should last about 6 to 12 weeks.
After treatment of the acute episode, your doctor will decide how long and with which dose 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 more orodispersible tablets than you should, take your next dose as prescribed. Do not take a smaller amount. Ask your doctor or pharmacist 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.

Stop using Jorveza and seek medical attention immediately if you notice any of the following symptoms:
- swelling of the face, particularly of the eyelids, lips, tongue or throat (angioedema) which may be symptoms of an allergic reaction.

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)
- fungal infections in the mouth and throat (symptoms can be white spots)

Common: may affect up to 1 in 10 people
- headache
- heartburn
- indigestion
- feeling sick (nausea)
- tingling or numbness in your mouth, dry mouth
- taste disorder, burning tongue
- upper abdominal (belly) pain
- tiredness
- decreased amount of the hormone cortisol in your blood
- dry eyes.
- difficulty in sleeping
- problems with tongue
- cold sore (oral herpes)

Uncommon: may affect up to 1 in 100 people
- anxiety, agitation
- dizziness
- high blood pressure
- cough, dry throat, sore throat, common cold
- abdominal (belly) pain, abdominal distension (bloating)
- difficulty swallowing
- inflammation of the stomach, ulcers in the stomach
- swelling of the lips
- rash, itching rash
- sensation of foreign body
- pain in the mouth or throat
- painful gums,

– decreased level of osteocalcin, weight gain.

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, 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)
– constipation, ulcers in the 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:
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

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

Jorveza 0.5 mg orodispersible tablet

- The active substance is budesonide. Each orodispersible tablet contains 0.5 mg of budesonide.
- The other ingredients are disodium hydrogen citrate, docusate sodium, macrogol (6000), magnesium stearate, mannitol (E 421), anhydrous monosodium citrate, povidone (K25), sodium hydrogen carbonate and sucralose (see also section 2, ”Jorveza contains sodium”).

Jorveza 1 mg orodispersible tablet

- 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 (E 421), 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

Jorveza 0.5 mg orodispersible tablet

Jorveza 0.5 mg orodispersible tablets are white, round, biplane. They are debossed with “0.5” on one side. They come in blisters in packs with 20, 60, 90, 100 or 200 orodispersible tablets.

Jorveza 1 mg orodispersible tablet

Jorveza 1 mg orodispersible tablets are white, round, biplane. They come in blisters in packs with 20, 30, 60, 90, 100 or 200 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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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 November 2022.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.