

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### Pr JORVEZA™

#### Budesonide Orodispersible Tablets

Read this carefully before you start taking JORVEZA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about JORVEZA.

#### What is JORVEZA used for?

- For the treatment of eosinophilic esophagitis. This is an inflammatory condition of the throat (esophagus) that causes problems or pain to swallow solid food.

#### How does JORVEZA work?

JORVEZA contains budesonide, which is used to decrease inflammation. As the tablet dissolves in your mouth, it mixes with your saliva, which is slowly swallowed and coats your throat (esophagus).

#### What are the ingredients in JORVEZA?

Medicinal ingredient: Budesonide

Non-medicinal ingredients: Anhydrous monosodium citrate, Disodium hydrogen citrate, Docusate sodium, Macrogol (6000), Magnesium stearate, Mannitol (E 421), Povidone (K25), Sodium hydrogen carbonate and Sucralose.

#### JORVEZA comes in the following dosage forms:

Blister.

#### 0.5 mg orodispersible tablets

Pack size: 60 orodispersible tablets.

#### 1 mg orodispersible tablets

Pack sizes: 20, 30 or 90 orodispersible tablets. Not all pack sizes may be available.

#### Do not use JORVEZA if you:

- Are allergic to budesonide or any of the other ingredients of this medicine
- Have active tuberculosis
- Have uncontrolled infections

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take JORVEZA. Talk about any health conditions or problems you may have, including if you:**

- Have high blood pressure

- Have diabetes, or if someone in your family has diabetes
- Have weakening of the bones (osteoporosis)
- Have ulcers in the stomach or first part of the small intestine (peptic ulcer)
- Have increased pressure in your eye (glaucoma) or eye problems such as clouding of the lens (cataracts) or if somebody in your family has glaucoma
- Have liver or kidney disease
- Are pregnant or breast-feeding, think you may be pregnant or planning to have a baby
- Are about to have an operation
- Are on other steroid treatment.

**Other warnings you should know about:**

Your immune system may be weakened while you are taking JORVEZA. Take the following steps to help avoid getting an infection:

- Keep away from people who have chicken pox or herpes zoster (shingles), if you have never had them. These illnesses may get worse during treatment with JORVEZA. If you do come into contact with chickenpox or shingles, see your doctor right away.
- Tell your doctor if you have not yet had measles.
- If you need to be vaccinated, please speak to your doctor first.
- If you know that you have a planned operation, please tell your doctor that you are using JORVEZA.

Tell your doctor if you have white spots in your mouth and throat or any signs of an infection. The symptoms of some infections can be unusual or less pronounced.

JORVEZA could affect the results of tests (ACTH stimulation test) performed by your doctor or in hospital. Tell your doctor that you are taking JORVEZA before any tests are carried out.

**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.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with JORVEZA:**

- Ketoconazole or itraconazole (to treat fungal infection)
- Clarithromycin or erythromycin (antibiotic medicine used to treat infections)
- Ritonavir and cobicistat (to treat HIV infections)
- Oestrogens (used for hormone replacement therapy or birth control)
- Cardiac glycoside such as digoxin (medicines used to treat heart conditions)
- Diuretics (to remove excess fluid from the body)

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

## How to take JORVEZA:

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

- JORVEZA should be taken immediately once removed from the blister package.
- Take JORVEZA after a meal
- Do NOT take any liquid or food with JORVEZA
- 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 oral solutions, sprays or chewable tablets at least 30 minutes before or after administration of JORVEZA. This will ensure that your medicine works properly.
- Place the JORVEZA tablet on the tip of your tongue and close your mouth. Press the tablet gently against the roof of your mouth until it has dissolved completely (this usually takes at least two minutes but may take up to 20 minutes). Swallow the dissolved material with saliva little by little while the tablet disintegrates
- Do not chew or swallow the undissolved tablet

## Usual adult dose:

The recommended dose for treatment of acute episodes is two 1 mg tablets per day, one 1 mg tablet in the morning and one 1 mg tablet in the evening after a meal (total daily dose: 2 mg budesonide). Your treatment should last about 6 weeks.

The recommended dose for prevention of further episodes is two 0.5 mg tablets per day. Take one 0.5 mg tablet in the morning and one 0.5 mg tablet in the evening (total daily dose: 1 mg budesonide).

After treatment of acute episodes, your doctor will decide how long you will continue the treatment, depending on your condition and your response to the treatment.

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 start to feel better.

## Overdose:

If you think you have taken too much JORVEZA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

## Missed Dose:

If you miss a dose, continue your treatment at the prescribed dosage. Do not use a double dose to make up for a forgotten dose.

## What are possible side effects from using JORVEZA?

These are not all the possible side effects you may feel when taking JORVEZA. If you experience any side effects that are not listed here, contact your healthcare professional. Typical side effects of cortisone preparations such as JORVEZA may occur which may affect all parts of the body, particularly when you use JORVEZA at high doses and for prolonged periods.

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

- Headache
- High blood pressure
- Inflammation of the stomach, ulcers in the stomach
- Heartburn
- Feeling sick (nausea)
- Tingling or numbness in the mouth
- Tiredness
- Indigestion
- Decreased amount of the hormone cortisol in your blood
- Difficulty in sleeping
- Dizziness
- Taste disorder
- Dry eyes
- Cough, dry throat
- Abdominal pain, upper abdominal pain
- Difficulty swallowing
- Burning tongue, swelling of the lips, dry mouth
- Rash, itching rash
- Sensation of foreign body
- Pain in the mouth or throat

The following side effects have been reported with medicines similar to JORVEZA, and can therefore also occur with JORVEZA:

- Restlessness with increased physical activity, anxiety, aggression
- Increased risk of blood clotting, inflammation of the blood vessels (associated with stopping cortisone use after long-term therapy)
- Indigestion, irritable stomach (dyspepsia), constipation, ulcers in the stomach or small intestine
- Rash from hypersensitivity reactions, red spots from bleeding in the skin, delayed wound healing, local skin reactions such as contact dermatitis, bruising
- General feeling of being ill

Contact your doctor if you experience blurred vision or other visual disturbances.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
Fungal infections in the throat/esophagus: white spots in mouth or throat		✓	
<b>REPORTED WITH MEDICINES SIMILAR TO JORVEZA</b>			
Changes in vision that may be signs of glaucoma (increased pressure in your eye), cataract (clouding of the lens of your eye), central serous chorioretinopathy (CSCR)		✓	
Brittle bones (osteoporosis), bone loss due to poor circulation of blood (osteonecrosis)	✓		
Cushing's syndrome: roundness of the face, weight gain, reduced glucose tolerance, high blood sugar, fluid retention in the tissues (e.g. swollen legs), increased excretion of potassium (hypokalemia), irregular periods in women, unwanted body hair in women, impotence, abnormal laboratory findings (reduced adrenal function), red stripes on the skin (stretch marks), acne	✓		
Hyperglycemia (high levels of sugar in the blood): increased thirst, headache, blurred vision, fatigue		✓	
Increased risk of infection (such as chicken pox and shingles)	✓		
Pancreatitis (inflammation of the pancreas): severe pain in the abdomen and back	✓		
Mood changes, such as depression, irritability or euphoria	✓		
Muscle and joint pain, muscle weakness, muscle twitching	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store at room temperature (15°C to 25°C). Store in the original package in order to protect from light and moisture.

**Keep out of reach and sight of children.**

### **If you want more information about JORVEZA:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website [www.avirpharma.com](http://www.avirpharma.com), or by calling 1-800-363-7988.

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