

Jorveza[®]

Budesonide 1 mg orally disintegrating tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about JORVEZA tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking this medicine against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What JORVEZA is used for

JORVEZA tablets contain the active ingredient, budesonide. Budesonide belongs to a group of medications called corticosteroids. JORVEZA tablets are used to treat eosinophilic oesophagitis (EoE) which is an inflammatory condition of the gullet (food pipe) that causes problems with swallowing food.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

JORVEZA is only available on a doctor's prescription.

There is not enough information to recommend the use of this medicine for children or adolescents.

Before you take JORVEZA

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing budesonide
- any ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take JORVEZA if you have uncontrolled infections or active tuberculosis.

Before you start to take it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking JORVEZA if you are pregnant or breastfeeding.

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver disease or kidney disease
- lung disease (tuberculosis)
- high blood pressure
- diabetes, when the level of sugar in the blood is too high
- disease which causes bones to become less dense, gradually making them weaker, more brittle and likely to break (osteoporosis)
- ulcer in stomach or duodenum
- glaucoma (high pressure in the eye)
- cataracts
- family history of diabetes or glaucoma
- any infections
- surgery or other stresses
- any other disease where use of steroids may have unwanted effects.

If you have not told your doctor about any of the above, tell him/her before you start taking JORVEZA tablets.

Tell your doctor if you are on other steroid treatments.

Keep away from people who have chicken pox or herpes zoster (shingles), if you have never had them.

Contact your doctor if you have been exposed to chicken pox, measles and shingles infections. These illnesses may become more severe when you take JORVEZA. JORVEZA treatment may need to be discontinued if you have these infections.

Tell your doctor if you have not yet had measles.

If you know that you need to be vaccinated please speak to your doctor first.

Tell your doctor if you get fungal infections in the mouth, throat (symptoms can be white spots) or in the gullet or if you think you have any infection during treatment with this medicine. The symptoms of some infections can be unusual or less pronounced.

If you know that you are due to have an operation please tell your doctor that you are taking JORVEZA.

If you have been treated with a stronger cortisone preparation before starting treatment with JORVEZA, your symptoms may reappear when the medicine is changed.

If this happens, contact your doctor.

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

JORVEZA contains 52 mg sodium (the main component of cooking/table salt) per daily dose. This is equivalent to approximately 2.6% of the recommended maximum daily dietary intake of sodium for an adult.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and JORVEZA may interfere with each other. These include:

- cardiac glycosides such as digoxin, medicines used to treat heart conditions
- diuretics, medicines used to treat excess fluid in your body
- ketoconazole and itraconazole, medicines used to treat fungal infections
- antibiotics such as clarithromycin and erythromycin, medicines used to treat infections
- ritonavir and cobicistat, medicines used to treat HIV infections
- oestrogens, contraceptive pill

These medicines may be affected by JORVEZA or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Avoid drinking grapefruit juice while you are taking JORVEZA as this can alter its effects.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take JORVEZA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Adults: The recommended dose is two tablets per day. Take one tablet in the morning and one tablet in the evening.

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.

How to take it

Place the 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 tablet breaks up.

Do NOT take any liquid or food with the tablet.

Do not chew or swallow the undissolved tablet.

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

When to take JORVEZA

Take your medicine twice a day (once in the morning and once at night) after a meal.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take JORVEZA

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.

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much JORVEZA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking JORVEZA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking JORVEZA tablets.

Tell any other doctors, dentists, and pharmacists who treat you

that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking JORVEZA, tell your doctor immediately.

Things you must not do

Do not stop taking JORVEZA or change the dosage without checking with your doctor.

Do not take JORVEZA to treat any other complaint unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Avoid drinking grapefruit juice.

Grapefruit juice contains some components that influence the metabolism of JORVEZA. This can worsen its side effects.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking JORVEZA.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the

following that are troublesome or ongoing:

- 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)
- headache
- feeling sick (nausea)
- pain in the upper middle part of the abdomen
- heartburn
- high blood pressure
- swelling of the lips
- tingling or numbness in your mouth
- tiredness, general feeling of being ill
- taste disorder

When JORVEZA is taken, side effects may occur which are typical of the more active cortisone preparations (Cushing-like properties). The side effects listed below depend on the dose, the period of treatment, whether there has been prior or accompanying treatment with other cortisone preparations and on the individual sensitivity.

- Cushing Syndrome: roundness of the face, weight gain, acne, increased risk of high blood sugar, fluid retention (e.g. swollen legs)
- slowed growth in children
- increased risk of infection
- irregular periods in women, male hair growth patterns in women, impotence
- mood changes such as depression, irritation or euphoria
- restlessness with increased physical activity, anxiety and aggression
- blurred vision (e.g. glaucoma and cataract)

- increased risk of blood clotting, disease of the blood vessels (associated with stopping steroid use after long term therapy)
- stomach complaints, gastric ulcers, pancreatitis and constipation
- muscle and joint pain, muscle weakness, muscle twitching
- bone weakness (osteoporosis), bone damage due to poor circulation of blood (osteonecrosis)
- rash from hypersensitivity reactions (allergic exanthema), formation of red stripes (striations) and bleeding in the skin, delayed wound healing, local skin reactions (such as contact dermatitis), bruising
- general feeling of being ill
- increased brain pressure with possible additional swelling of the optic disk in adolescents.

If any of the following happen, stop taking JORVEZA and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- shortness of breath
- itchy rash or hives.

These are the symptoms of an allergic reaction.

These are serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking JORVEZA

Storage

Keep your medicine in the original container.

If you take it out of its container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

Do not store JORVEZA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

JORVEZA 1mg: white or almost white, round tablets with a smooth surface and facet.

They are available in blisters of 20, 30, 60 and 90 tablets*.

* Not all pack sizes may be marketed

Ingredients

Active ingredients:

JORVEZA 1mg – 1mg budesonide

Inactive ingredients:

- magnesium stearate

- sodium acid citrate
- sodium dihydrogen citrate
- docusate sodium
- sucralose
- sodium bicarbonate
- mannitol
- macrogol 6000
- povidone

Supplier

JORVEZA® is supplied in Australia by:

Dr Falk Pharma Australia Pty Ltd
815 Pacific Highway,
Chatswood, NSW 2067
Phone: 1800 DRFALK (373 255)

JORVEZA® is supplied in New Zealand by:
Pharmacy Retailing (NZ) Ltd t/a
Healthcare Logistics

58 Richard Pearse Drive,
Airport Oaks, Mangere 2022

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