

Jorveza®

Budesonide 0.5 mg and 1 mg orally disintegrating tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking JORVEZA?

JORVEZA tablets contain the active ingredient, budesonide. JORVEZA tablets are used in adult patients to treat eosinophilic oesophagitis (EoE) which is an inflammatory condition of the gullet (food pipe) that causes problems with swallowing food.

For more information, see Section [1. Why am I taking JORVEZA?](#) in the full CMI.

2. What should I know before I take JORVEZA?

Do not take if you have ever had an allergic reaction to JORVEZA tablets or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I take JORVEZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with JORVEZA tablets and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take JORVEZA?

- Adults: The recommended dose for treatment of acute episodes is two 1 mg tablets per day. Take one 1 mg tablet in the morning and one in the evening.
- The recommended dose for prevention of further episodes is two 0.5 mg tablets (1 mg budesonide) per day or two 1 mg tablets (2 mg budesonide) per day, depending on your response to the treatment. Take one tablet in the morning and one tablet in the evening. Your doctor will decide which dose is best for you.

More instructions can be found in Section [4. How do I take JORVEZA?](#) in the full CMI.

5. What should I know while taking JORVEZA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using JORVEZA tablets. • If you become pregnant while using this medicine, tell your doctor immediately.
Things you should not do	• Do not take JORVEZA tablets to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop using JORVEZA or change the dosage without checking with your doctor.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery.

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using JORVEZA tablets. • If you become pregnant while using this medicine, tell your doctor immediately.
Looking after your medicine	• Keep JORVEZA in their original packaging until it is time to take them. • Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect from light and moisture. • 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.

For more information, see Section [5. What should I know while taking JORVEZA?](#) in the full CMI.

6. Are there any side effects?

- All medicines can have side effects. If they do occur, they are usually minor and temporary. The most common side effects of taking JORVEZA are: fungal infections in the gullet (food pipe), mouth and throat, headache, feeling sick (nausea), heartburn, indigestion, 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 and cold sore (oral herpes).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Jorveza®

Active ingredient: *budesonide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using JORVEZA tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JORVEZA.**

Where to find information in this leaflet:

- [1. Why am I taking JORVEZA?](#)
- [2. What should I know before I take JORVEZA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take JORVEZA tablets?](#)
- [5. What should I know while taking JORVEZA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking JORVEZA?

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.

2. What should I know before I take JORVEZA?

Warnings

Do not take JORVEZA if:

- you are allergic to budesonide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- Do not take this medicine if you have uncontrolled infections or active tuberculosis.
- Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other conditions especially the following:
 - liver disease or kidney disease
 - lung disease (e.g. 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 (cloudy area in your eye)
 - family history of diabetes or glaucoma
 - any infection
 - recent or planned surgery
 - other stresses
 - any other disease where use of corticosteroids may have unwanted effects
- are on other corticosteroid treatments.
 - 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 JORVEZA. The symptoms of some infections can be unusual or less pronounced when taking JORVEZA.
 - have been exposed to chicken pox, measles and shingles infections. These illnesses may become more severe when you take JORVEZA.
 - have not yet had measles.
 - know that you need to be vaccinated, please speak to your doctor first.
 - know that you are due to have an operation, please tell your doctor that you are taking JORVEZA.
 - have been treated with a stronger corticosteroid preparation before starting treatment with JORVEZA, your symptoms may reappear when the medicine is changed. If this happens, contact your doctor.

- experience blurred vision or other visual disturbances.

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

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 seek urgent medical attention. These may be signs of an allergic reaction, which may also include rash and itching.

JORVEZA 0.5 mg and 1 mg contains 26 mg of sodium (the main component of cooking/table salt) in each tablet. Therefore, the maximum daily dose of sodium from either strength when taken as advised (2 x 1 mg or 2 x 0.5 mg tablets) is 52 mg per day. 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with JORVEZA and affect how it works.

- 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 they may affect how well JORVEZA works. You may need different doses of your medicine(s) or you may need to take different medicines. Your doctor or pharmacist will advise you if this is required.

Avoid drinking grapefruit juice. Grapefruit juice contains some components that influence the metabolism (break-down) of JORVEZA. This can worsen its side effects.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JORVEZA.

4. How do I take JORVEZA tablets?

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

How much to take

- The recommended dose for treatment of acute episodes is two 1 mg tablets per day. Take one 1 mg tablet in the morning and one in the evening.
- The recommended dose for prevention of further episodes is two 0.5 mg tablets (1 mg budesonide) per day or two 1 mg tablets (2 mg budesonide) per

day, depending on your response to the treatment. Take one tablet in the morning and one tablet in the evening. Your doctor will decide which dose is best for you.

Speak to your doctor if you want to interrupt or end your JORVEZA treatment early. It is important that you do not stop taking JORVEZA without talking to your doctor.

Keep taking JORVEZA until your doctor tells you to stop, even if you feel better.

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 to take JORVEZA

- Take the JORVEZA tablet immediately once removed from the blister package.
- Take JORVEZA after a meal.
- 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 disintegrated completely (this takes between 2 and 5 minutes on average but may take up to 10 minutes or longer in some patients). Saliva will be produced while

the JORVEZA tablet is disintegrating. Swallow the disintegrated material slowly, as the tablet breaks up.

- Do NOT take any liquid or food with the tablet.
- Do not chew or swallow the tablet if not disintegrated.
- 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.

For Australian patients, an 'Instructions for Use' video is available by scanning the QR code, which covers the same dosing procedure detailed above.



For NZ patients this 'Instructions for Use' video is available at

<https://hcp.dr.falkpharma.com.au/jorveza-instructions-for-use-nz/>

How long to take JORVEZA

- Initially, your treatment should last about 6 to 12 weeks.

After this initial treatment, your doctor will decide for how long and which dose (1 mg/day or 2 mg/day) you should continue to take, depending on your condition and your response to the treatment.

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

If you forget to take JORVEZA

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 that 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 JORVEZA

If you think that you have taken too much JORVEZA no emergency medical treatment is required. If you have any concerns, you should:

- contact your doctor, or
- phone the Poisons Information Centre (by calling 13 11 26)

5. What should I know while taking JORVEZA?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking JORVEZA.

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

It may affect other medicines used during surgery.

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

Things you should not do

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

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

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

Driving or using machines

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

Looking after your medicine

- Keep JORVEZA in the original packaging until it is time to take them. If you take out of the packaging before you plan to dose, they may not keep well.
- Store below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store JORVEZA in a cool dry place away from moisture, heat or sunlight, for example, do not store it:

- in the bathroom or near a sink; or
in the car or on window sills.

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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, speak to your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
When taking JORVEZA: Very common side effects include: • fungal infections in the gullet (which can cause pain or discomfort when swallowing) • fungal infections in the mouth and throat (possible signs include white spots in the mouth or throat) Common side effects include: • headache • feeling sick (nausea) • heartburn • indigestion • tingling or numbness in your mouth, dry mouth	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
● 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 side effects include: ● high blood pressure ● anxiety, agitation ● dizziness ● 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	

Less serious side effects	What to do
• rash, itching rash • sensation of foreign body • pain in the mouth or throat • painful gums • decreased level of osteocalcin, weight gain.	

Serious side effects

Serious side effects	What to do
Symptoms of allergic reaction: • swelling of the face, particularly of the eyelids, lips, tongue or throat (angioedema) • shortness of breath • itchy rash or hives.	Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these symptoms.

The following side effects have been reported with medicines which are in the same class as JORVEZA tablets (corticosteroids). These side effects are typical for systemically acting preparations. As JORVEZA tablets act locally, the risk of these class effects

occurring with this medicine are generally expected to be lower than with systemically acting corticosteroids.

Possible class effects of systemically acting corticosteroids are:

- 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 and aggression
- blurred vision (e.g. glaucoma and cataract)
- increased risk of blood clotting, disease of the blood vessels (associated with stopping corticosteroid use after long term therapy)
- ulcers in the small intestine, 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, bruising

- general feeling of being ill
- increased brain pressure with possible additional swelling of the optic disk in adolescents.

These side effects are typical for systemic corticosteroids, such as prednisolone. Due to the local action of JORVEZA tablets, the risk of systemic adverse reactions is generally lower than when taking systemically acting corticosteroids.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What JORVEZA tablets contains

Active ingredient (main ingredient)	Budesonide 1 mg or 0.5 mg
Other ingredients (inactive ingredients)	magnesium stearate sodium acid citrate sodium dihydrogen citrate docusate sodium sucralose sodium bicarbonate mannitol macrogol 6000 povidone
Potential allergen	sucralose

Do not take this medicine if you are allergic to any of these ingredients.

What JORVEZA tablets looks like

JORVEZA 1 mg orally disintegrating tablets: 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

JORVEZA 0.5 mg orally disintegrating tablets: white, round tablets debossed with “0.5” on one side and smooth on the other side.

They are available in blisters of 20, 60, 100 and 200 tablets*.

* Not all pack sizes may be marketed.

Australian Registration Number:

JORVEZA 1 mg orally disintegrating tablets:

AUST R 322645

JORVEZA 0.5 mg orally disintegrating tablets:

AUST R 350996

Who distributes JORVEZA tablets

JORVEZA® is supplied in Australia by:

Dr Falk Pharma Australia Pty Ltd

9 Help Street

Chatswood, NSW 2067

Australia

Phone: 1800 DRFALK (373 255)

JORVEZA® is supplied in New Zealand by:

Dr Falk Pharma New Zealand Ltd

29 Northcroft Street

Takapuna, Auckland 0622

New Zealand

Phone: 0800 44 88 69

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