

Package leaflet: Information for the user

Budenofalk 2mg/dose Rectal Foam budesonide

Read all of this leaflet carefully before you start using 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 Budenofalk Rectal Foam is and what it is used for
2. What you need to know before you use Budenofalk Rectal Foam
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1. What Budenofalk Rectal Foam is and what it is used for

Budenofalk Rectal Foam contains the active substance budesonide, a type of locally acting steroid used to treat inflammatory bowel disease.

Budenofalk Rectal Foam is used for the treatment of:

- Inflammation of the rectum (back passage) and the lower part of the colon (sigmoid colon), known by doctors as ulcerative colitis.

2. What you need to know before you use Budenofalk Rectal Foam

Do not use Budenofalk Rectal Foam

- if you are **allergic** to budesonide or any of the other ingredients of this medicine (listed in section 6)
- if you have a **severe liver disease** (liver cirrhosis).

Warnings and precautions

Talk to your doctor before using Budenofalk Rectal Foam if you have:

- tuberculosis
- high blood pressure
- diabetes, or if diabetes has been diagnosed in your family
- brittle bones (osteoporosis)
- ulcers in the stomach or first part of the small intestine (peptic ulcer)
- increased pressure in your eye (glaucoma) or eye problems such as clouding of the lens (cataracts) or if glaucoma has been diagnosed in your family
- severe liver problems

Typical effects of cortisone preparations may occur which may affect all parts of the body, particularly when you use Budenofalk Rectal Foam at high doses and for prolonged periods (see section 4. Possible side effects).

Further precautions during treatment with Budenofalk Rectal Foam

- Tell your doctor if you have an infection. The symptoms of some infections can be atypical or less pronounced.
- Keep away from people who have chickenpox or herpes zoster (shingles), if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.
- 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.
- If you know that you are due to have an operation please tell your doctor that you are using Budenofalk Rectal Foam.
- If you have been treated with a stronger cortisone preparation before starting treatment with Budenofalk Rectal Foam, 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.

Other medicines and Budenofalk Rectal Foam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular:

- **cardiac glycosides** such as digoxin (medicines used to treat heart conditions)
- **diuretics** (to remove excess fluid from the body)
- **ketoconazole or itraconazole** (to treat fungal infections)
- **antibiotic** drugs used to treat infections (such as clarithromycin)
- **carbamazepine** (used in the treatment of epilepsy)
- **rifampicin** (for treating tuberculosis)
- **oestrogens or oral contraceptives**

Some medicines may increase the effects of Budenofalk Rectal Foam and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Budenofalk Rectal Foam could affect the results of tests performed by your doctor or in hospital. Tell your doctor that you are using Budenofalk Rectal Foam before any tests are carried out.

Budenofalk Rectal Foam with food and drink

You should **not** drink **grapefruit juice** whilst you are using this medicine as this can alter its 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 for advice before using this medicine.

You should only use Budenofalk Rectal Foam during pregnancy if your doctor tells you to.

Budesonide passes in small amounts into the breast milk. If you are breast-feeding you should only use Budenofalk Rectal Foam if your doctor tells you to.

Driving and using machines

Budenofalk Rectal Foam is not expected to affect your ability to drive or operate machinery.

Budenofalk Rectal Foam contains propylene glycol, cetyl alcohol and cetostearyl alcohol

This medicinal product contains 600.3 mg propylene glycol in each actuation of Budenofalk Rectal Foam. Propylene glycol may cause skin irritation.

Cetyl alcohol and cetostearyl alcohol (component of emulsifying wax) may cause local skin reactions (e.g. contact dermatitis).

3. How to use Budenofalk Rectal Foam

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

The recommended dose is

Dose for adults over 18 years of age

The usual dose is 1 spray actuation per day, either in the morning or to be used at bedtime.

Emptying your bowels before using Budenofalk Rectal Foam produces the best results.

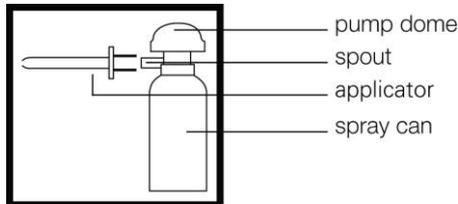
Use in children and adolescents

Budenofalk Rectal Foam should not be used in children under 18 years of age, because there is very limited experience with Budenofalk Rectal Foam in this age group.

Method of administration

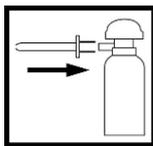
This medicine may only be used rectally, so it has to be inserted through the anus. It is **not intended to be taken by mouth**. Do not swallow.

Picture of the spray can

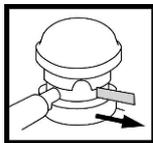


The applicators are in a special rail. Please hold the rail firmly and pull the applicator out sharply.

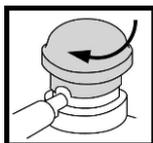
Preparing to use the foam



Push applicator firmly onto the spout of the spray can.
Shake the spray can for about 15 seconds to mix the contents.

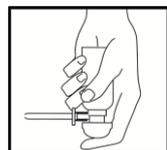


Before the first use, remove the safety lock (plastic flap) from under the pump dome.

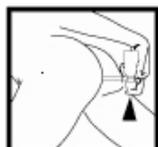


Twist the dome on the top of the spray can until the semi-circular gap underneath is in line with the applicator. The spray can is now ready for use.

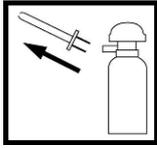
Using the foam



Place your index finger on the top of pump dome and turn the can upside down. Note that the spray can will only work properly when held with the pump dome pointing down as vertically as possible.



Stand with one foot on a stool or chair or lie on your side with the lower leg stretched out and the upper leg bent for balance. Insert the applicator into your rectum as far as possible. Push the pump dome down fully once and then slowly release it – the foam comes out of the spray can when you release the dome. Keep the applicator in place for 10 - 15 seconds before taking it out. This ensures the full dose is delivered into the rectum and no foam is spilt.



After administering the foam, remove the applicator and dispose of it with your household waste in the plastic bag provided. Use a new applicator for the next application.

In order to prevent the inadvertent loss of foam from the spray can between applications turn the pump dome around so that the semi-circular gap faces the opposite direction to the spout.

- Wash your hands and try not to empty your bowels until the next morning.
- If you go to hospital or see another doctor or dentist tell them you are using this medicine.

Duration of treatment

How long you will use the medicine depends upon your condition. Your doctor will decide how long you are to continue the medication.

Acute episodes of inflammatory bowel disease (ulcerative colitis) generally subside after 6 - 8 weeks.

If you think that the effect of Budenofalk Rectal Foam is too strong or too weak, talk to your doctor.

If you use more Budenofalk Rectal Foam than you should

If you have used too much medicine on one occasion, use your next dose as prescribed. Do not use a smaller amount. Contact a doctor if you are in doubt, so he or she can decide what to do; take the carton and this leaflet with you if possible.

If you forget to use Budenofalk Rectal Foam

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

If you stop using Budenofalk Rectal Foam

Speak to your doctor if you want to interrupt or end your treatment early. It is important that you do not stop using your medicine abruptly as it could make you ill. Keep using your medicine until your doctor tells you to stop, even if you start to 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.

If you get any of the following symptoms after using this medicine, you should contact your doctor immediately:

- infection
- headache

- changes in behaviour such as depression, irritability, euphoria, restlessness, anxiety or aggression

The following side effects have also been reported:

Common: may affect up to 1 in 10 people

- burning or pain in the rectum
- Cushing's syndrome – e.g. with roundness of the face, weight gain, reduced glucose tolerance, high blood sugar, high blood pressure, fluid retention in the tissues (e.g. swollen legs), increased excretion of potassium (hypokalaemia), irregular periods in women, unwanted body hair in women, impotence, abnormal laboratory findings (reduced adrenal function), red stripes on the skin (stretch marks), acne.
- indigestion, irritable stomach (dyspepsia)
- increased risk of infection
- muscle and joint pain, muscle weakness, muscle twitching
- brittle bones (osteoporosis)
- headache
- mood changes, such as depression, irritability or euphoria
- rash from hypersensitivity reactions, red spots from bleeding in the skin, delayed wound healing, local skin reactions such as contact dermatitis

Uncommon: may affect up to 1 in 100 people

- an increase in appetite
- changes to the blood (increase in erythrocyte sedimentation rate, increase in the number of white blood cells)
- nausea, abdominal pain, wind, tingling or numbness in the abdomen, anal fissure, mouth ulcers, frequent need to empty the bowels, rectal bleeding
- ulcers in the stomach or small intestine
- changes in liver function parameters
- changes in pancreatic function, changes in adrenal hormones
- urinary tract infections
- giddiness, disturbance of smell
- sleeplessness, restlessness with increased physical activity, anxiety
- increased sweating, weakness

Rare: may affect up to 1 in 1,000 people

- blurred vision
- inflammation of the pancreas
- bone loss due to poor circulation of blood (osteonecrosis)
- aggression
- bruising

Very rare: may affect up to 1 in 10,000 people

- slowed growth in children
- constipation
- increased pressure in the brain, possibly with increased pressure in the eye (swelling of the optic disk) in adolescents
- increased risk of blood clotting, inflammation of the blood vessels

- (associated with stopping cortisone use after long-term therapy)
- tiredness, general feeling of being ill

These side effects are typical of steroid medication and most of them can also be expected for treatments with other steroids. They may occur depending on your dose, duration of treatment, whether you have had or are having treatment with other cortisone preparations, and your individual susceptibility.

Some of these unwanted effects were only reported after long-term use of oral budesonide.

In general, the risk of side effects with Budenofalk Rectal Foam is lower than with systemically acting (affecting the whole body) cortisone preparations due to its local action.

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

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:

Republic of Ireland:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Budenofalk Rectal Foam

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

Do not use this medicine after the expiry date which is stated on the carton and on the pressurised container. The expiry date refers to the last day of that month.

The contents of the container must be used within 4 weeks after first opening.

Do not store above 25°C.

Do not refrigerate or freeze

The container is pressurised and contains flammable propellant. Do not expose to temperature higher than 50°C, protect from direct sunlight. Do not pierce or burn, even when empty.

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 to protect the environment.

6. Contents of the pack and other information

What Budenofalk Rectal Foam contains

The active substance is budesonide. Each dose of foam contains 2 mg budesonide.

The other ingredients are cetyl alcohol, emulsifying wax, purified water, disodium edetate, macrogol stearyl ether, propylene glycol, citric acid monohydrate and n-butane, isobutane and propane as propellants.

What Budenofalk Rectal Foam looks like and contents of the pack

Budenofalk Rectal Foam is a white to pale white, creamy, firm foam and is presented in a pressurised container.

Budenofalk Rectal Foam is available in packs containing 1 pressurised container, 14 applicators and 14 plastic bags or in packs containing 2 pressurised containers, 28 applicators and 28 plastic bags, for the hygienic disposal of the applicators.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark, Finland, Greece, Ireland, Romania, Sweden, United Kingdom:
Budenofalk
Austria: Budo-San

Italy: Intesticort
Spain: Intestifalk

This leaflet was last revised in 02/2021