

BUDENOFALK® FOAM ENEMA

Budesonide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BUDENOFALK foam enema. 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 risks of you using BUDENOFALK against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What BUDENOFALK is used for

BUDENOFALK foam enema contains the active ingredient, budesonide. Budesonide belongs to a group of medications called corticosteroids.

BUDENOFALK foam enema is used to treat ulcerative colitis (inflammation) of the rectum (back passage) and the lower part of the large bowel.

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.

BUDENOFALK 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 use BUDENOFALK

When you must not use it

Do not use BUDENOFALK if you have an allergy to:

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

Some 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 use BUDENOFALK if you suffer from a severe liver disease (liver cirrhosis).

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use 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 using BUDENOFALK if you are pregnant or breastfeeding.

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

- liver disease
- lung disease
- 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
- ulcer in stomach or duodenum
- glaucoma (high pressure in the eye)
- cataracts
- family history of diabetes or glaucoma
- any infections
- any stresses
- any other disease where use of corticosteroids may have unwanted effects.

If you have not told your doctor about any of the above, tell him/her before you start using BUDENOFALK foam enema.

Chicken pox, measles and shingles may become more severe when you use BUDENOFALK. Contact your doctor if you have been exposed to any of these infections.

Taking other medicines

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

Some medicines and BUDENOFALK 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 rifampicin, medicines used to treat infections
- ritonavir, medicine used for treating HIV infections
- carbamazepine, medicine used for treating epilepsy
- rifampicin, medicine used to treat tuberculosis
- contraceptive pill
- cholestyramine, medicine used to reduce cholesterol level
- cimetidine, medicine to reduce stomach acid.

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

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

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

How to use BUDENOFALK

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 use

Adults and the elderly:

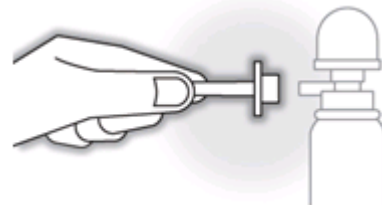
Apply one actuation daily, corresponding to 2 mg budesonide.

BUDENOFALK 2mg foam enema can be applied in the morning or evening.

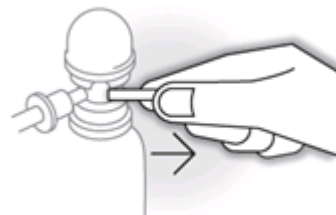
How to use it

If possible, go to the toilet and empty your bowels before using your enema.

- Wash your hands thoroughly with soap and water.
- Push the applicator firmly onto the spout of the spray can.



- Shake the can for 15 seconds to mix the contents.
- Remove the safety tab from under the pump dome.

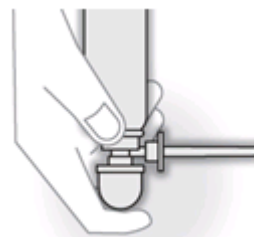


- Twist the dome on top of the canister until the semi-circular gap underneath it is in line with the nozzle.

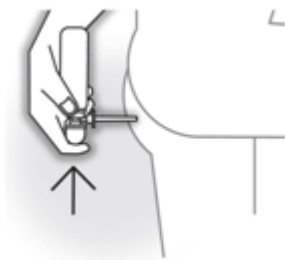


The spray can is now ready for use.

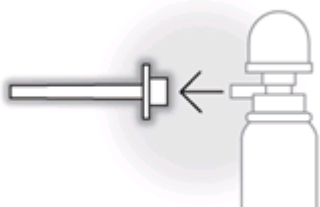
- Place your forefinger on top of the pump dome. Turn the spray can upside down. The pump dome must be **pointing down**.



- Stand with one foot on the floor and raise the other foot onto a chair or stool.
- Insert the applicator into the rectum as far as comfortable. To administer a **dose** of BUDENOFALK foam enema, push the pump dome fully once and hold for 5 seconds then release it. Wait 15 seconds for the foam to be delivered.



9. Withdraw the applicator from the rectum.
10. Remove the applicator from the spout of the spray can and dispose of it in the plastic bag provided as domestic waste.



11. Wash your hands thoroughly and try not to empty your bowels again for as long as possible.

You may experience a little discomfort and a feeling of urgency to empty your bowels immediately after enema insertion. This is normal and expected due to the inflammation present within the bowel. Try to resist this urge to empty your bowels for as long as possible. This feeling will subside as treatment continues and the inflammation decreases.

When to use it

Use your medicine at about the same time each day. Using it at the same time each day will have the best effect. It will help you remember when to use it.

How long to use it

The duration of treatment will be decided by your doctor. In general, the acute episode subsides after 6 to 8 weeks. After this you should stop using BUDENOFALK foam enema.

BUDENOFALK helps control your condition but does not cure it. Therefore, you must continue to use BUDENOFALK for as long as your doctor tells you to.

If you forget to use it

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

Otherwise, use it as soon as you remember and then go back to taking your medicine as you would normally.

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

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

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

If you use 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 the nearest hospital, if you think that you, or anyone else, may have used too much BUDENOFALK. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using BUDENOFALK

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using BUDENOFALK foam enema.

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 this medicine, tell your doctor immediately.

Things that you must not do

Do not use BUDENOFALK foam enema to treat any 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 your BUDENOFALK or change the dosage without checking with your doctor.

Side effects

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

Like all medicines, BUDENOFALK may have some 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.

Common side effects (that affect less than 1 in 10 patients):

- Burning or pain in the rectum

Uncommon side effects (that affect less than 1 in 100 patients):

- anaemia or other changes to the blood
- headache, giddiness, disturbance of smell
- urinary tract infections
- high blood pressure
- sleeplessness
- nausea, abdominal pain, dyspepsia, wind, tingling in the abdomen, anal fissure, mouth rash, urgent need to empty the bowels, haemorrhoids, rectal bleeding
- changes in liver function
- changes in pancreatic function, changes in adrenal hormones
- acne, increased sweating
- tiredness, increase in body weight, increase in appetite.

When BUDENOFALK is used, 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, increased risk of high blood sugar, fluid retention, reduced 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
- 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 pain and bone weakness (osteoporosis), loss of bone and cartilage (aseptic bone necrosis)
- 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)
- isolated cases: increased brain pressure with possible additional swelling of the optic disk in adolescents

Most of these unwanted effects were noted after long-term use of oral steroids and so these effects will be less with BUDENOFALK foam enema.

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

- Allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing

Other less common events, which have been reported with budesonide, include:

- an abnormal increase in the number of white blood cells in the blood as a result of infection
- sedimentation rate increase caused by inflammation.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

After using BUDENOFALK

Storage

Keep BUDENOFALK foam enema in its original packaging until it is time to use it.

Keep BUDENOFALK foam enema in a cool dry place where the temperature stays below 25°C.

Do not refrigerate or freeze.

Protect from direct sunlight.

Contains FLAMMABLE gas – Keep away from flames or sparks.

Use within 4 weeks of first opening.

Do not store BUDENOFALK or any other medicine in the bathroom or near a sink. Do not leave BUDENOFALK 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 using BUDENOFALK or the expiry date has passed, ask your pharmacist what to do with any foam enema that is left over.

Do not pierce or burn the can even when empty.

Product description

What it looks like

BUDENOFALK foam enema is a white to pale white, creamy, firm foam and is supplied in a pressurised container.

Ingredients

Each dose/actuation of BUDENOFALK foam enema contains 2 mg of the active ingredient, budesonide.

Each container of BUDENOFALK foam enema also contains cetyl alcohol, wax-emulsifying, purified water, disodium edetate, Steareth-10, propylene glycol, citric acid monohydrate and butane, isobutane and propane as propellants.

BUDENOFALK 2 mg foam enemas are available in the following packs:

- One pressurised container with 14 applicators and 14 plastic bags
- Two pressurised containers, with 28 applicators and 28 plastic bags

Not all pack sizes are currently available in Australia.

Plastic bags are for the hygienic disposal of the applicators.

Manufacturer/Supplier

BUDENOFALK foam enemas are made in Germany by:

Dr. Falk Pharma GmbH
Leinenweberstr. 5
79108 Freiburg, Germany

and supplied in Australia by:

Orphan Australia Pty Ltd
(a member of the Aspen Australia group of companies)
34-36 Chandos Street
St Leonards NSW 2065

This leaflet was revised in February 2017.

Australian Registration Number:

BUDENOFALK foam enema 2 mg AUST R
179575

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