

Package leaflet: Information for the patient

Budenofalk 4 mg suppositories 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

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1. What Budenofalk 4 mg suppositories are and what they are used for

Budenofalk 4 mg suppositories contain the active substance budesonide, a type of locally acting steroid used to treat inflammatory bowel disease.

Budenofalk 4 mg suppositories are used in adult patients for the treatment of acute episodes of inflammatory disease of the rectum (ulcerative proctitis).

2. What you need to know before you use Budenofalk 4 mg suppositories

Do not use Budenofalk 4 mg suppositories

- 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 or pharmacist before using Budenofalk 4 mg suppositories 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
- liver problems
- kidney problems

Further precautions during treatment with Budenofalk 4 mg suppositories

- 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 4 mg suppositories.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Budenofalk 4 mg suppositories could affect the results of tests performed by your doctor or in hospital. Tell your doctor that you are using Budenofalk 4 mg suppositories before any tests are carried out.

Elderly

Elderly patients should be closely monitored for side effects.

Children and adolescents

Budenofalk 4 mg suppositories should not be used in children and adolescents under 18 years of age. The use of this medicine in patients younger than 18 years of age has not yet been studied.

Other medicines and Budenofalk 4 mg suppositories

Tell your doctor or pharmacist if you are using, have recently used or might use 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)
- **clarithromycin, an antibiotic** used to treat infections
- **carbamazepine** (used in the treatment of epilepsy)
- **rifampicin** (for treating tuberculosis)
- **oestrogens or oral contraceptives**

Some medicines may increase the effects of Budenofalk 4 mg suppositories and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Budenofalk 4 mg suppositories 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 4 mg suppositories 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 4 mg suppositories if your doctor tells you to.

Driving and using machines

Budenofalk 4 mg suppositories are not expected to affect your ability to drive or operate machinery.

3. How to use Budenofalk 4 mg suppositories

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

Dosage

The recommended dose is one Budenofalk 4 mg suppository daily.

Method of administration

This medicine may only be used rectally, so it has to be inserted through the anus. Do NOT take it by mouth.

Budenofalk 4 mg suppositories should be administered at bedtime, so the suppository remains in place for as long as possible.

How to insert the suppository

- If possible, the suppository should be inserted after a bowel movement.
- Wash your hands thoroughly.
- Carefully remove the suppository from the strip just before use.



- Warming the suppository shortly beforehand with the palms of your hands may make insertion easier.



- Hold the suppository between the thumb and index finger.



- Lie down on your side in a comfortable position and insert the suppository gently and deeply into the back passage (rectum) with the pointed side first.



- Wash your hands thoroughly again.

Duration of treatment

Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition. Acute episodes of inflammatory bowel disease (ulcerative proctitis) generally subside after 6 - 8 weeks.

If you use more Budenofalk 4 mg suppositories than you should

If you have used too many suppositories 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 4 mg suppositories

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 4 mg suppositories

Speak to your doctor if you want to interrupt or end your treatment early. 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.

The following side effects have been reported during the use of Budenofalk 4 mg suppositories:

Very common: may affect more than 1 in 10 people

- decreased amount of the hormone cortisol in your blood.

Uncommon: may affect up to 1 in 100 people

- reduced function of the adrenal glands (small glands next to the kidneys)
- headache
- flushing
- abdominal pain, flatulence, severe abdominal pain because of an acute inflammation of the pancreas
- rash
- changes to menstrual periods such as irregular periods.

The following side effects have been reported and are typical with medicines similar to Budenofalk 4 mg suppositories (corticosteroids) and can therefore also occur with this medicine. The frequency of these events is currently not known:

- increased risk of infection
- Cushing's syndrome, which is associated with too much corticosteroid and causes roundness of the face, weight gain, high blood sugar (hyperglycaemia), build-up of fluid in the tissues (e.g. swollen legs), reduced potassium level in the blood (hypokalaemia), unwanted body hair in women, impotence, stretch marks on the skin, acne.
- mood changes, such as depression, irritability or euphoria
- restlessness with increased physical activity, anxiety, aggression
- blurred vision
- increased risk of blood clots, inflammation of the blood vessels, high blood pressure
- dyspepsia, ulcers in the stomach and small intestine, constipation
- allergic skin rash, red spots from bleeding in the skin, delayed wound healing, skin reactions such as contact dermatitis, bruising
- muscle and joint pain, muscle weakness, muscle twitching
- weakening of the bones (osteoporosis), bone damage due to poor circulation of blood (osteonecrosis)
- tiredness and general feeling of being ill.

These side effects are typical of steroid medication. 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.

If you have been treated with a stronger cortisone preparation before starting treatment with Budenofalk 4 mg suppositories, your symptoms may reappear when the medicine is changed. If this happens, contact your doctor.

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:

Ireland:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Budenofalk 4 mg suppositories

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 blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Budenofalk 4 mg suppositories contain

- The **active substance** is budesonide
- The **other ingredients** are ascorbyl palmitate E 304(i) and hard fat.

What Budenofalk 4 mg suppositories look like and contents of the pack

Budenofalk 4 mg suppositories are white, torpedo-formed suppositories (approximately 2 cm length) with a smooth surface.

Budenofalk 4 mg suppositories are available in packs containing 12, 30 or 60 suppositories.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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