

## Consumer Medicine Information

### **What is in this leaflet**

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This leaflet answers some common questions about BUDENOFALK enteric capsules. 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 taking BUDENOFALK enteric capsules against the benefits they expect it will have for you.

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

### **What BUDENOFALK is used for**

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BUDENOFALK enteric capsules contain the active ingredient, budesonide. Budesonide belongs to a group of medications called corticosteroids. BUDENOFALK enteric capsules are used to treat Crohn's disease affecting the ileum and/or the ascending colon (inflammation of the last section of the small bowel and/or the first section of the large bowel) for 8 weeks.

**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 take it**

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#### ***When you must not take it***

**Do not take 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.

BUDENOFALK enteric capsules contain lactose and sucrose. This may cause a problem if you have intolerance to some sugars.

**Do not take BUDENOFALK if you suffer from a severe liver disease (liver cirrhosis).**

**Do not take 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 taking this medicine, talk to your doctor.**

#### ***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 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 (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
- any stresses
- intolerance to sugars
- 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 BUDENOFALK enteric capsules.**

**Contact your doctor if you have been exposed to chicken pox, measles and shingles infections.**

They may become more severe when you take BUDENOFALK.

**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 taking BUDENOFALK.**

If you have been treated with a stronger cortisone preparation before starting treatment with BUDENOFALK, 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.**

#### ***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, medicines used to treat infections
- ritonavir and cobicistat medicines used to treat HIV infections

- carbamazepine, medicine used to treat epilepsy
- rifampicin, medicine used to treat tuberculosis
- contraceptive pill
- cholestyramine, medicine used to reduce cholesterol level
- cimetidine, medicine used 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 take 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 taking this medicine.

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### **How to take it**

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**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 and the elderly:**  
One BUDENOFALK 3 mg enteric capsule three times a day (morning, midday and evening), or three BUDENOFALK 3 mg enteric capsules once daily in the morning.

BUDENOFALK treatment should be terminated by gradual reduction of your dose over the last two weeks. The dosage should be reduced to two capsules daily (one in the morning and one in the evening) for one week. In the last week, only one capsule should be taken in the morning.

**Once you have started taking BUDENOFALK, do not stop taking it abruptly.**

#### ***How to take it***

**Swallow the capsules whole with a glass of water. Do not chew or crush the capsules.**

**If you have difficulty swallowing the capsules, open the capsule and take the granules with plenty of liquid. Do not chew or crush the granules.**

#### ***When to take it***

Take BUDENOFALK enteric capsules about 30 minutes before 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 it***

BUDENOFALK enteric capsules may be used for up to 8 weeks for each episode of Crohn's disease.

#### ***If you forget to take 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, take it as soon as you remember and then go back to taking your medicine as you would normally.**

**Do not take 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 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 the nearest hospital, if you think that you or anyone else may have taken too much BUDENOFALK. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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### **While you are taking it**

#### ***Things you must do***

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

**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 take BUDENOFALK enteric capsules 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 taking BUDENOFALK or change the dosage without checking with your doctor.**

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### **Side effects**

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

**Tell your doctor or pharmacist immediately if you notice any of the following:**

- signs or symptoms of an infection
- headache
- changes in behaviour such as depression, irritability, euphoria, restlessness, anxiety or aggression.

**Tell your doctor or pharmacist if you notice any of the following that are troublesome or ongoing:**

- abdominal pain
- pain in the upper middle part of the abdomen
- diarrhoea / soft stools
- high blood pressure
- acne
- tiredness, general feeling of being ill.

When BUDENOFALK 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, increased risk of high blood sugar, fluid retention, reduced growth
- 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.

**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.

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

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

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## After taking it

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### **Storage**

**Keep BUDENOFALK enteric capsules in their original packaging until it is time to take them.**

**Keep your capsules in a cool dry place where the temperature stays below 30°C.**

**Do not store it 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 BUDENOFALK or the expiry date has passed, ask your pharmacist what to do with any capsules that are left over.

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## Product description

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### **What it looks like**

BUDENOFALK 3 mg enteric capsules are pink opaque capsules containing round white pellets. Available in blister packs of 90.

### **Ingredients**

Each BUDENOFALK enteric capsule contains 3 mg of the active ingredient, budesonide.

Each BUDENOFALK enteric capsule also contains lactose monohydrate, sugar spheres (sucrose), triethyl citrate, purified talc, povidone, methacrylic acid copolymer, ammonio methacrylate copolymer, gelatin, sodium

lauryl sulphate, as well as the colourings titanium dioxide, iron oxide red, iron oxide black and erythrosine.

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## Sponsor

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