

# BUDENOFALK® capsules

## Budesonide

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### 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.

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## 1. Why am I taking BUDENOFALK Capsules?

BUDENOFALK capsules contain the active ingredient, budesonide. BUDENOFALK 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. For more information, see Section [1. Why am I taking BUDENOFALK Capsules?](#) in the full CMI.

## 2. What should I know before I take BUDENOFALK Capsules?

Do not take if you have ever had an allergic reaction to BUDENOFALK capsules 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 BUDENOFALK Capsules?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with BUDENOFALK capsules 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 BUDENOFALK Capsules?**

- The recommended dose is one BUDENOFALK capsule three times a day (morning, midday and evening), or three BUDENOFALK capsules once daily in the morning.
- This medicine may only be used orally.

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

## 5. What should I know while taking BUDENOFALK Capsules?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking <b>BUDENOFALK</b> capsules.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take <b>BUDENOFALK</b> capsules to treat any other complaints unless your</li></ul>

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	<p>doctor tells you to.</p> <ul style="list-style-type: none"> <li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li> <li>• Do not stop taking</li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>• <b>Remind any doctor, dentist or pharmacist you visit that you are taking BUDENOFALK capsules.</b></li> <li>• <b>If you become pregnant while taking this medicine, tell your doctor immediately.</b></li> </ul>
	<p>BUDENOFALK capsules or change the dosage without checking with your doctor.</p>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• This medicine is not expected to affect your</li> </ul>

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	<p>ability to drive a car or operate machinery.</p>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>• <b>Keep BUDENOFALK capsules in their original packaging until it is</b></li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are taking BUDENOFALK capsules.</b></li> <li>● <b>If you become pregnant while taking this medicine, tell your doctor immediately.</b></li> </ul>
	<p>time to take them.</p> <ul style="list-style-type: none"> <li>● Keep your capsules in a cool and dry place where the temperature stays below 30C.</li> <li>● Keep it where children</li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>• <b>Remind any doctor, dentist or pharmacist you visit that you are taking BUDENOFALK capsules.</b></li> <li>• <b>If you become pregnant while taking this medicine, tell your doctor immediately.</b></li> </ul>
	<p>cannot reach it.</p> <ul style="list-style-type: none"> <li>• A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.</li> </ul>

For more information, see Section [5. What should I know while taking BUDENOFALK Capsules?](#) 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 taking BUDENOFALK capsules are: abdominal pain, pain in the upper middle part of the abdomen, diarrhoea / soft stools, high blood pressure, acne, tiredness, general feeling of being ill. 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.

# BUDENOFALK® capsules

Active ingredient(s): *budesonide*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I taking BUDENOFALK capsules?

BUDENOFALK capsules contain the active ingredient, budesonide distributed within enteric-coated (gastric resistant) granules. Budesonide belongs to a group of medications called corticosteroids.

**BUDENOFALK 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.**

## 2. What should I know before I take BUDENOFALK capsules?

### Warnings

**Do not take BUDENOFALK capsules 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 use this medicine.
- Do not take this medicine 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.

## **Check with your doctor if you:**

- have any other conditions and taking medicines
  - 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.
- have an infection. The symptoms of some infections can be atypical or less pronounced.
- have been exposed to chicken pox, measles and shingles infections. These illnesses may become more severe when you take BUDENOFALK capsules.
- have not yet had measles.
- need to be vaccinated, please speak to your doctor first.

- know you are due to have an operation, please tell your doctor that you are taking BUDENOFALK capsules.
- have been treated with a stronger corticosteroid preparation before starting treatment with BUDENOFALK capsules, your symptoms may reappear when the medicine is changed. If this happens, contact your doctor.
- experience blurred vision or other visual disturbances.

BUDENOFALK capsules are not recommended for use in children or adolescents.

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

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 BUDENOFALK capsules 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 BUDENOFALK capsules 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, 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 capsules or they may affect how well BUDENOFALK capsules work. 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 while you are taking BUDENOFALK capsules as this can alter its effects.

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

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

## **4. How do I take BUDENOFALK capsules?**

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

### **How much to take**

- **Adults and the elderly:**

One BUDENOFALK capsule three times a day (morning, midday and evening), or three BUDENOFALK capsules once daily in the morning.

BUDENOFALK capsules 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 capsules, do not stop taking it abruptly.**

## **When to take**

Take BUDENOFALK 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 to take**

**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.**

Due to the gastro-resistant coating being on the granules rather than the capsules, there is no change in how the medicine works by swallowing the capsules whole versus opening the capsules and swallowing the granules directly.

## How long to take

Your doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition. BUDENOFALK capsules may be used for up to 8 weeks for each episode of Crohn's disease.

## If you forget to take

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.**

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

If you think that you have taken too many BUDENOFALK capsules no emergency 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 BUDENOFALK capsules?**

### **Things you should do**

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking BUDENOFALK capsules.**

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

It may affect other medicines used during surgery.

**If you become pregnant while taking BUDENOFALK capsules, tell your doctor immediately.**

### **Things you should not do**

Do not take BUDENOFALK 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 capsules 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.

## **Looking after your medicine**

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

Keep your BUDENOFALK capsules in a cool and 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.

## **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
<p><b>When using BUDENOFALK capsules:</b></p> <ul style="list-style-type: none"> <li>• abdominal pain</li> <li>• pain in the upper middle part of the abdomen</li> <li>• diarrhoea / soft stools</li> <li>• high blood pressure</li> <li>• acne</li> <li>• tiredness, general feeling of being ill.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• signs or symptoms of an infection</li> <li>• headache</li> <li>• changes in behaviour such as depression, irritability, euphoria,</li> </ul>	<p><b>Call your doctor or pharmacist immediately if you notice any of these symptoms.</b></p> <p><b>Call your doctor immediately or go straight to the</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>restlessness, anxiety or aggression.</p> <p><b>Symptoms of allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● swelling of the limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing</li> </ul>	<p><b>Emergency Department at your nearest hospital if you notice any of these symptoms.</b></p>

**The following side effects have been reported with medicines which are in the same class as BUDENOFALK capsules (corticosteroids). These side effects listed below depend on the dose, the period of treatment, whether there has been prior or accompanying treatment with other corticosteroid preparations and on the individual sensitivity.**

**Possible class effects are:**

- 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.

These side effects are typical for systemic corticosteroids, such as prednisolone. Data shows that the frequency of systemic adverse reactions is lower with BUDENOFALK capsules.

**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 that you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://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 BUDENOFALK capsules contain**

<b>Active ingredient (main ingredient)</b>	<b>Budesonide 3 mg</b>
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate sugar spheres (sucrose) triethyl citrate purified talc povidone methacrylic acid copolymer ammonio methacrylate copolymer gelatin sodium lauryl sulphate titanium dioxide iron oxide red

<b>Active ingredient (main ingredient)</b>	<b>Budesonide 3 mg</b>
	iron oxide black erythrosine.

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

## **What BUDENOFALK capsules looks like**

BUDENOFALK capsules are pink opaque capsules containing round white pellets.

BUDENOFALK capsules are approved in blister packs of 9 and 10 (starter packs), 50 and 90.

## **Who distributes BUDENOFALK capsules**

Dr Falk Pharma Australia Pty Ltd,

9 Help Street

Chatswood NSW 2067

Australian Registration Number: AUST R 179566

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