

Package leaflet: Information for the user

Budenofalk 3mg gastro-resistant capsules budesonide

Read all of this leaflet carefully before you start taking 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 3mg capsules are and what they are used for

Budenofalk 3mg capsules contain the active substance budesonide, a type of locally acting steroid used to treat chronic inflammatory diseases of the intestine and the liver.

Budenofalk 3mg capsules are used in the treatment of:

- **Crohn's disease:** mild to moderate acute attacks of chronic inflammation of the intestine affecting the lower part of the small bowel (ileum) and/or upper part of the large bowel (the ascending colon).
- **Microscopic colitis:** a disease with the subtypes collagenous and lymphocytic colitis, characterised by chronic inflammation of the large bowel typically accompanied by chronic watery diarrhoea.
- **Autoimmune hepatitis:** a disease with chronic inflammation of the liver.

2. What you need to know before you take Budenofalk 3mg capsules

DO NOT take Budenofalk 3mg capsules:

- 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 taking Budenofalk 3mg capsules 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

Budenofalk 3mg capsules are not suitable for patients with Crohn's disease affecting the upper gastrointestinal tract.

Sometimes this disease may cause symptoms outside the intestine (e.g. affecting the skin, eyes and joints) which are unlikely to respond to this medicine.

Typical effects of cortisone preparations may occur which may affect all parts of the body, particularly when you take Budenofalk 3mg capsules at high doses and for prolonged periods (see section 4. Possible side effects).

Further precautions during treatment with Budenofalk 3mg capsules

- Tell your doctor if you have an infection. The symptoms of some infections can be unusual 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 3mg capsules.
- If you have been treated with a stronger cortisone preparation before starting treatment with Budenofalk 3mg capsules, 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.
- If you have autoimmune hepatitis, your doctor will carry out liver function tests regularly and will adjust the dosage of this medicine periodically.

Other medicines and Budenofalk 3mg capsules

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**
- **cimetidine** (used to inhibit the production of acid in the stomach)

Some medicines may increase the effects of Budenofalk 3mg capsules and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you take **cholestyramine** (for hypercholesterolemia and also used to treat diarrhoea) or **antacids** (for indigestion) in addition to Budenofalk 3mg capsules, take these medicines **at least 2 hours apart**.

Budenofalk 3mg capsules could affect the results of tests performed by your doctor or in hospital. Tell your doctor that you are taking Budenofalk 3mg capsules before any tests are carried out.

Budenofalk 3mg capsules with food and drink

You should **not** drink **grapefruit juice** whilst you are taking 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 taking this medicine.

You should only take Budenofalk 3mg capsules 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 take Budenofalk 3mg capsules if your doctor tells you to.

Driving and using machines

Budenofalk 3mg capsules are not expected to affect your ability to drive or operate machinery.

Budenofalk 3mg capsules contain sucrose and lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Budenofalk 3mg capsules

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

Crohn's disease

Take three capsules once daily in the morning or one capsule 3 times a day (morning, midday and evening), unless your doctor instructs you otherwise.

Duration of treatment

Your treatment should last about 8 weeks.

Microscopic colitis (collagenous and lymphocytic colitis)

Treatment of acute inflammation

Take three capsules once daily in the morning, unless your doctor instructs you otherwise.

Maintenance treatment

Maintenance treatment should only be started if symptoms reappear after stopping initial therapy. Depending on the course of your illness, your doctor will decide how many capsules you should take per day. Usually, the dose is two capsules once

daily in the morning (a total of 6 mg budesonide per day). Alternatively, take two capsules in the morning on the first day and one capsule in the morning on the second day (corresponding to an average amount of 4.5 mg budesonide per day). Continue taking your medicine alternating the daily dose of two capsules and one capsule.

Duration of treatment

Treatment of acute inflammation should last about 8 weeks. The duration of maintenance treatment is determined by your doctor. Maintenance treatment is normally administered for up to 12 months. If it is indicated, your doctor may extend the treatment duration.

Autoimmune hepatitis

Treatment of acute inflammation

Take one capsule 3 times a day (morning, midday and evening), unless your doctor instructs you otherwise. Depending on the results of laboratory examinations, your doctor will decide how long you should take three capsules per day.

Maintenance treatment

Take one capsule 2 times a day (morning and evening), unless your doctor instructs you otherwise. Depending on the results of laboratory examinations, your doctor will decide how long you should take two capsules per day.

Please note that in most cases your doctor will prescribe Budenofalk 3mg capsules together with azathioprine, a medicine that works by reducing the body's immune response.

Duration of treatment

Depending on the results of examinations of your blood and liver tissue, your doctor will decide how long you should take this medicine and how many capsules per day you should take.

Use in children (all indications)

Budenofalk 3mg capsules should NOT be used in children under 12 years of age. There is only limited experience with the use of this medicine in children older than 12 years of age.

Method of administration

Budenofalk 3mg capsules are for oral use only.

The capsules are to be swallowed whole, with a glass of water about ½ hour before meals. Do not chew the capsules.

If you take more Budenofalk 3mg capsules than you should

If you have taken too much medicine on one occasion, take your next dose as prescribed. Do not take 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 take Budenofalk 3mg capsules

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

If you stop taking Budenofalk 3mg capsules

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

Your doctor will probably want to reduce your dose gradually over the course of two weeks.

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 taking 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

- 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), abdominal pain
- 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

- ulcers in the stomach or small intestine
- restlessness with increased physical activity, anxiety

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.

If you have been treated with a stronger cortisone preparation before starting treatment with Budenofalk 3mg capsules, 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:

Ireland

HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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

5. How to store Budenofalk 3mg capsules

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.

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

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 protect the environment.

6. Contents of the pack and other information

What Budenofalk 3mg capsules contain

The **active substance** is budesonide. Each capsule with gastro-resistant pellets contains 3 mg of budesonide.

The **other ingredients** are ammonio methacrylate copolymer (type A) (Eudragit RL), ammonio methacrylate copolymer (type B) (Eudragit RS), lactose monohydrate, maize starch, methacrylic acid-methyl methacrylate copolymer (1:1) (Eudragit L 100), methacrylic acid-methyl methacrylate copolymer (1:2) (Eudragit S 100), povidone K25, purified water, sucrose, talc, triethyl citrate, gelatin, erythrosine (E127), titanium dioxide (E171), red and black iron oxide (E172), sodium laurilsulphate (*see also end of Section 2 for further, important information on lactose and sucrose*).

What Budenofalk 3mg capsules look like and contents of the pack

Budenofalk 3mg capsules are pink coloured gastro-resistant hard capsules contained in blister strips.

Budenofalk 3mg capsules are available in pack sizes of 10, 50, 90, 100 or 120 – not all 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, Ireland, Sweden, United Kingdom: Budenofalk

France: MIKICORT

Italy: Intesticort

Spain: Intestifalk

This leaflet was last revised in 12/2019.