Package leaflet: information for the user

Budenofalk® 9mg gastro-resistant granules

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:

1. What Budenofalk granules are and what they are used for
2. What you need to know before you take Budenofalk granules
3. How to take Budenofalk granules
4. Possible side effects
5. How to store Budenofalk granules
6. Contents of the pack and other information

1. What Budenofalk granules are and what they are used for

Budenofalk granules contain the active substance budesonide, a type of locally acting steroid used to treat chronic inflammatory diseases of the intestine.

Budenofalk granules 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).

- **Acute episodes of microscopic colitis:** a disease with the subtypes collagenous and lymphocytic colitis, characterised by chronic inflammation of the large bowel which is typically accompanied by chronic watery diarrhoea.

2. What you need to know before you take Budenofalk granules

DO NOT take Budenofalk granules
- if you are **allergic** to budesonide or any of the other ingredients in 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 granules 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 granules 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 granules at high doses and for prolonged periods (see section 4. Possible side effects).

Further precautions during treatment with Budenofalk granules
- 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 granules.
- If you have been treated with a stronger cortisone preparation before starting treatment with Budenofalk granules, 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.

Other medicines and Budenofalk granules
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 granules 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 hypercholesterolaemia and also used to treat diarrhoea) or **antacids** (for indigestion) in addition to Budenofalk granules, take these medicines **at least 2 hours apart**.

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

Budenofalk granules 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 granules during pregnancy if your doctor tells you to.

Budesonide passes in small amounts into the breast milk. If you are breastfeeding you should only take Budenofalk granules if your doctor tells you to.

Driving and using machines
Budenofalk granules are not expected to affect your ability to drive or operate machinery.

Budenofalk granules contain sucrose, lactose and sorbitol
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 900 mg sorbitol in each sachet. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

3. How to take Budenofalk granules

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

The recommended dose is:
Crohn's disease and microscopic colitis
Adults (over 18 years)
Take one sachet in the morning unless your doctor instructs you otherwise.

Use in children and adolescents
Budenofalk granules should NOT be used in **children** under 18 years of age.

Method of administration
Budenofalk granules are for oral use only.
You should take the Budenofalk granules about ½ hour before breakfast. Place the granules directly on the tongue and then swallow them with a glass of water. **Do not chew** the granules as they may not work properly.

Duration of treatment
Your treatment should last about 8 weeks.

Your doctor will decide how long you are to continue the medication, depending on your condition.

If you take more Budenofalk granules 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 granules

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 granules
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 abruptly 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, from one sachet every day to one sachet every other day for at least 2 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 granules, 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 listed below.

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 granules

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 sachet. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 granules contain
The **active substance** is budesonide. Each sachet with gastro-resistant granules contains 9 mg of budesonide.
The **other ingredients** are ammonio methacrylate copolymer (type A) (Eudragit RL), ammonio methacrylate copolymer (type B) (Eudragit RS), citric acid, lactose monohydrate, lemon flavour, magnesium stearate, methacrylic acid-methyl methacrylate copolymer (1:1) (Eudragit L 100), methacrylic acid-methyl methacrylate copolymer (1:2)

(Eudragit S 100), povidone K25, sucralose, sugar spheres (consisting of sucrose and maize starch), sorbitol (E420), talc, triethyl citrate, xanthan gum (see section 2 for further information on lactose, sucrose and sorbitol).

What Budenofalk granules look like and contents of the pack
Budenofalk granules are white to off-white coloured gastro-resistant granules and white to pale yellow powder with lemon flavour, filled into one sachet.
Budenofalk granules are available in pack sizes of 15, 20, 30, 50 and 60 sachets – not all may be marketed

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