PACKAGE LEAFLET: Information for the user

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Budenofalk® is and what it is used for
2. Before you use Budenofalk®
3. How to take Budenofalk®
4. Possible side effects
5. Storing Budenofalk®

Budenofalk®

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

The other ingredients are:
Povidone K25, lactose monohydrate, sucrose, talc, maize starch, methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), ammonio methacrylate copolymer type B, ammonio methacrylate copolymer type A (= Eudragit L, S, RS and RL), triethyl citrate, titanium dioxide (E171), purified water, gelatin, erythrosine (E127), iron (II,III) oxide (E172), iron (III) oxide (E172), sodium lauryl sulphate.

Budenofalk® is available in blister packs of 50 and 100 gastro-resistant hard capsules.

1. What Budenofalk® is and what it is used for

Budenofalk® is one of the locally acting, non-halogenated glucocorticosteroids used to treat inflammatory diseases of the intestine such as Crohn's disease.

Budenofalk® is manufactured and marketed by:

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Budenofalk® is used for the treatment of:

Mild to moderate attacks of Crohn's disease (a chronic inflammatory disease of the intestine) affecting the ileum and/or parts of the large intestine (ascending colon).

Please note:

Treatment with Budenofalk® does not appear useful in patients with Crohn's disease affecting the upper gastro-intestinal tract.

Because of its local action, Budenofalk® is unlikely to be effective against non-intestinal symptoms of the disease e.g. those affecting the skin, eyes or joints.

2. Before you use Budenofalk®

Do not use Budenofalk® in case of:
- hypersensitivity to budesonide or any of the other ingredients of Budenofalk®
- local infections of the intestine caused by bacteria, fungi, amoebae or viruses
- cirrhosis of the liver with signs of portal hypertension e.g. in the late stage of a cirrhosis spreading from the bile ducts

Take special care with Budenofalk®:
If you are suffering from one or more of the following diseases: tuberculosis, high blood pressure, diabetes, brittleness of the bones (osteoporosis), gastric or duodenal ulcers (peptic ulcer), glaucoma, cataract or a family history of diabetes or glaucoma.

Chickenpox, shingles and measles can be very severe or even life-threatening during treatment with Budenofalk®. If you are one of those patients who have never had these illnesses, you must at all avoid close contact with someone suffering from one of these illnesses. If you have become infected, then treatment with corresponding immunoglobulins may be indicated. If you develop chickenpox, treatment with an antiviral drug should be considered. In this case it is essential that you contact your doctor.

You must not be inoculated with live vaccines during treatment with Budenofalk®. The formation of antibodies after inoculation with other types of vaccine (killed vaccines) can be reduced.

Simultaneous treatment with ketoconazole or other drugs that inhibit CYP3A-enzymes should be avoided (see „Taking other medicines").

In severe disorders of liver function – as is the case with other glucocorticosteroids – the excretion of budesonide during treatment with Budenofalk® can be reduced and the bioavailability of the drug in the circulation can be increased. Therefore these patients should first be excluded from treatment with budesonide.

Budenofalk® may reduce the response of the hypothalamo-pituitary-adrenal axis to stress. For this reason, during surgery or other situations of stress, a systemically acting glucocorticosteroid should be taken at the same time.

Since treatment with Budenofalk® leads to lower blood levels than are usual with systemically acting steroids, symptoms of the disease can recur when such steroids are replaced by Budenofalk®.

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking Budenofalk®.

Children:
Due to inadequate experience, Budenofalk® should not be used in children.

Pregnancy and breast-feeding:
Budenofalk® may only be used in pregnancy, especially in the first three months, on the specific instruction by the doctor. Women of childbearing age must make sure that they are not pregnant before starting treatment with Budenofalk® and must take suitable measures to prevent contraception during treatment. Since it is not known whether or not Budenofalk® passes into breast-milk, breast-feeding must not take place during treatment with Budenofalk®.

Driving and using machines:
No effects on the ability to drive and use machines have been observed.

Taking other medicines
- *Cardiac glycosides:*
  The action of the glycoside can be increased by the deficiency of potassium.
- *Saluretics:*
  The excretion of potassium can be increased.
- *Cytochrome P450 3A:*
  CYP3A-inhibitors, such as ketoconazole, ritonavir, troleandomycin, erythromycin, ciclosporin, grapefruit juice:
  The action of the corticosteroid can be increased.
  CYP3A-inductors, such as carbamazepine and rifampicin, can reduce both the systemic and also the local action of budesonide on the intestinal mucosa. Therefore the dose of budesonide may need to be adjusted.
  Dosage adjustment may also be required if CYP3A-substrates, e.g. ethinylestradiol are taken at the same time.

It has been reported that plasma levels and the effects of corticosteroids are increased in women taking estrogens or oral contraceptives („the pill") at the same time. This interaction has not been observed after intake of low-dose contraceptives.

Simultaneous use of cimetidine and budesonide can result in a slight increase in plasma levels of budesonide, but this is of no clinical relevance. Simultaneous use of omeprazole does not change the pharmacokinetics of budesonide.

Possible interactions with steroid-binding artificial resins such as colestyramine and antacids cannot be ruled out. The action of budesonide can be weakened on simultaneous administration of Budenofalk® and therefore these preparations should be taken at least 2 hours apart.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. How to take Budenofalk®

Always take Budenofalk® exactly as instructed by your doctor. You should check with your doctor or pharmacist if you are unsure.

Unless otherwise prescribed by your doctor, take 1 hard capsule (containing 3 mg of budesonide) three times daily (morning, midday, evening).

Swallow the hard capsules whole with plenty of fluid (e.g. a glass of water) about 1/2 hour before meals.

Patients who have difficulty in swallowing capsules may open them and just take the gastro-resistant pellets whole with plenty of fluid. This will not affect the effectivity of Budenofalk®.

The duration of treatment is generally 8 weeks and as a rule the full effect is reached after 2-4 weeks.

Budenofalk® must not be stopped abruptly, but discontinued gradually.

If you have the impression that the effect of Budenofalk® is too strong or too weak, please talk to your doctor.

If you have taken more Budenofalk® than you should:
To date, no cases of overdose with budesonide are known. In view of the properties of Budenofalk® containing the active substance budesonide, an overdosage with toxic consequences is extremely unlikely.

If you have taken more Budenofalk® than you should, do not take fewer Budenofalk® hard capsules the next time, but just continue the treatment with the prescribed dose.

If you have taken too little Budenofalk® or have forgotten to take any at all:
Do not take more Budenofalk® the next time, but just continue the treatment with the prescribed dose.
If you realise that you have forgotten a dose shortly after the due time, you can take a dose straight away. If the next dose is already due, just take the prescribed dose, not a double one.

Effects when the treatment with Budenofalk® is stopped:
Always ask your doctor first before you decide to interrupt treatment with Budenofalk®, or stop them prematurely because – for example – side effects have occured. It should be noted that Budenofalk® must not be stopped abruptly, but withdrawn gradually.

4. Possible side effects

Like all medicines, Budenofalk® can have side effects.

There have been spontaneous reports of the following side effects:
In very rare to isolated cases (< 1/10 000):
Accumulation of fluid in the legs, Cushing's syndrome, increased intracranial pressure possibly also with swelling of the optic disk in adolescents, diffuse muscle pain and weakness, osteoporosis (brittleness of the bones).
Some of these side effects have been observed after long-term use.

Occasionally, side effects that are typical of systemically acting glucocorticoids can occur (Cushingoid properties). These side effects depend on the dose, the duration of treatment, simultaneous or previous treatment with other glucocorticosteroids and individual sensitivity.

Clinical studies have shown that the frequency of glucocorticoid associated side effects is lower (by about 50%) with Budenofalk® than with equivalent doses of prednisolone. Nevertheless, the occurrence of side effects that are typical of glucocorticosteroids cannot be ruled out.

- *Skin and connective tissue:*
  Skin rash due to hypersensitivity reactions (allergic exanthema), streaking and bleeding in the skin, acne, delayed wound healing, contact dermatitis
- *Muscles and skeleton:*
  Wasting of bones and cartilage (aseptic bone necrosis)
- *Eyes:*
  Increase in intraocular pressure, opacity of lens (cataract)
- *Central nervous system, mental state:*
  Depression, irritability, euphoria
- *Gastro-intestinal tract:*
  Stomach complaints, gastric ulcer, inflammation of the pancreas
- *Metabolism:*
  Cushing's syndrome: moon-face, truncal obesity, diabetes, increase in blood sugar levels, accumulation of fluid in tissues, increased excretion of potassium, inactivity resp. shrinkage of the adrenal cortex, delayed growth in children, disturbances in sex hormone secretion (e.g. absence of menstrual periods, male hair pattern in women, impotence)
- *Circulation and blood vessels:*
  High blood pressure, increased risk of thrombosis, diseases of the blood vessels (withdrawal syndrome after long-term therapy)
- *Immune system:*
  Weakening of the immune system
  (e.g. increased risk of infection)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. Storing Budenofalk®

Keep medicines out of the reach and sight of children.
Do not store above 25 °C.

Do not use after the expiry date stated on the carton and on the blister strips.

Date of information:

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