PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

BUDENOFALK 3 mg CAPSULES

Budesonide

Contains sugar:

Lactose monohydrate: 12 mg/capsule

Sucrose: 276 mg/capsule

Read all of this leaflet carefully before you start taking BUDENOFALK 3 mg CAPSULES

- Keep this leaflet. You may need to read it again
- if you have further questions, please ask your doctor or pharmacist
- BUDENOFALK 3 mg CAPSULES has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What BUDENOFALK 3 mg CAPSULES is and what it is used for
2. What you need to know before you take BUDENOFALK 3 mg CAPSULES
3. How to take BUDENOFALK 3 mg CAPSULES
4. Possible side effects
5. How to store BUDENOFALK 3 mg CAPSULES
6. Contents of the pack and other information

1. What BUDENOFALK 3 mg CAPSULES is and what it is used for

Each capsule contains 3 mg budesonide as the active ingredient, a type of locally acting steroid used to treat chronic inflammatory diseases of the intestine and the liver.

It is 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 3 mg CAPSULES

Do not take BUDENOFALK 3 mg CAPSULES if you:

- You have an allergy (hypersensitivity) to budesonide or any of the other ingredients in this medicine (listed in **section 6**)
- you have a **severe liver disease** (liver cirrhosis).

Warnings and precautions

Tell your doctor or pharmacist if any of the following apply to you:

Before you start taking BUDENOFALK 3 mg CAPSULES, tell your doctor 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.

Further precautions:

- 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 3 mg CAPSULES
- if you have been treated with a stronger cortisone preparation before starting treatment with BUDENOFALK 3 mg CAPSULES, your symptoms may reappear when the medicine is changed. If this happens, contact your doctor.

Taking BUDENOFALK 3 mg CAPSULES with other medicines

Always tell our healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines.)

Inform your doctor if you take the following medicines:

- **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** medicines used to treat infections (such as clarithromycin)
- **Ritonavir** (for HIV infections)
- **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 3 mg 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 3 mg CAPSULES, take these medicines at least 2 hours apart.

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

Taking BUDENOFALK 3 mg CAPSULES with food and drink

You should not drink grapefruit juice whilst you are taking this medicine as this can alter its effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast feeding your baby while using BUDENOFALK 3 mg CAPSULES please consult your doctor, pharmacist or other health care professional for advice.

Budesonide passes in small amounts into the breast milk. If you are breast-feeding, you should only take BUDENOFALK 3 mg CAPSULES if your doctor tells you to.

Driving and using machines

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

It is not always possible to predict to what extent BUDENOFALK 3 mg CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment until they are aware of the measure to which BUDENOFALK 3 mg CAPSULES affects them.

BUDENOFALK 3 mg CAPSULES 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 this medicine.

3. How to take BUDENOFALK 3 mg CAPSULES

BUDENOFALK 3 mg CAPSULES is for you only. Please do not give it to anyone else, even if they have the same symptoms as you**.**

Always take BUDENOFALK 3 mg CAPSULES exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

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 you 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 3 mg 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.

Children (all indications)

BUDENOFALK 3 mg 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 3 mg 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 as they may not work properly.

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 impair the effectiveness of BUDENOFALK 3 mg CAPSULES.

Duration of treatment

Your treatment should last about 8 weeks.

Your doctor will decide how long you are to continue the medicine, depending on your condition. Do not stop treatment early because that can cause adverse effects. If you have the impression that the effect of BUDENOFALK 3 mg CAPSULES is too strong or too weak, tell your doctor or pharmacist.

If you take more BUDENOFALK 3 mg CAPSULES than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BUDENOFALK 3 mg CAPSULES

If it is still a long time before your next dose, take the dose as soon as you remember, and then take it as you would normally the next day. If it is almost time for your next dose, just wait and take the next dose as you normally would.

Do not use a double dose to make up for a forgotten dose.

If you stop taking BUDENOFALK 3 mg 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, first from three to two capsules for 1 week (one in the morning and one in the evening) and then only one capsule a day in the last week of treatment (taken in the morning).

4. Possible side effects

Not all side effects reported for BUDENOFALK 3 mg CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUDENOFALK 3 mg CAPSULES, please consult your health care provider for advice.

If any of the following happens, stop taking BUDENOFALK 3 mg CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BUDENOFALK 3 mg CAPSULES. You may need urgent medical attention or hospitalisation.

BUDENOFALK 3 mg CAPSULES can have side effects. The following side-effects may occur:

- Infection
- headache

- changes in behaviour or psychiatric effects for example depression, irritability and feeling of well-being.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- Cushing's syndrome – e.g. roundness of the face, weight gain, reduced glucose tolerance, high blood sugar, fluid retention, increased excretion of potassium (hypokalaemia), reduced growth in children, irregular periods in women, unwanted body hair in women, impotence, abnormal laboratory findings (reduced adrenal function), swelling of the legs (because of fluid retention, oedema)
- 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.

Less frequent side effects:

- Ulcers in the stomach or small intestine
- restlessness with increased physical activity, anxiety
- blurred vision,
- inflammation of the pancreas
- bone loss due to poor circulation of blood (osteonecrosis)

- aggression
- bruising
- 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 medicines 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 3 mg CAPSULES, your symptoms may reappear when the medicine is changed.

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

Reporting of side effects

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. You can furthermore report side effects directly to the marketing authorisation holder via: Customer Care: 080 222 6662. By

reporting side effects, you can help provide more information on the safety of BUDENOFALK 3 mg CAPSULES.

5. How to store BUDENOFALK 3 mg CAPSULES

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package.

Do not use after the expiry date stated on the label/carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

What BUDENOFALK 3 mg CAPSULES contains

Each capsule contains 3 mg budesonide as the active ingredient.

The other inactive 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), methacrylic acid-methyl methacrylate copolymer (1:2) (Eudragit S), povidone K25, sucrose, talc, triethyl citrate

The capsule shell contains:

Black iron oxide (E 172), erythrosine (E 127), gelatin, purified water, red iron oxide (E 172), sodium laurilsulphate, titanium dioxide (E 171).

The product contains sugar:

Lactose monohydrate: 12 mg/capsule

Sucrose: 276 mg/capsule.

What BUDENOFALK 3 mg CAPSULES looks like and contents of the pack

Pink capsules (size 1) containing white, round pellets, packed in Aluminium/PVC/PVDC blister strips that are packed in a cardboard carton in 10, 20, 50, 90, 100 or 120 capsules.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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