

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Budeson[®] 4 mg suppositories

Active ingredient:

Each suppository of **Budeson 4 mg suppositories** contains 4 mg budesonide. For the list of the additional ingredients see section 6.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. What is the medicine intended for?

The medicine is intended for short-term treatment of mild to moderate acute ulcerative inflammation of the large bowel (ulcerative colitis) that is limited to the rectal area (ulcerative proctitis), in adult patients.

Therapeutic class: a steroidal (glucocorticoid) anti-inflammatory medicine with local activity.

The medicine contains the active ingredient budesonide, which is a type of locally acting corticosteroid used to reduce inflammation in the bowel (inflammatory bowel disease). Acute ulcerative proctitis is an inflammation of the rectum causing ulceration and bleeding.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for the list of additional ingredients, see section 6).
- You have a severe liver disease (liver cirrhosis).

Special warnings regarding the use of the medicine:

Before treatment with Budeson 4 mg suppositories, tell the doctor if you suffer from:

Tuberculosis; high blood pressure; diabetes, or if you have a family history of diabetes; brittle bones (osteoporosis); ulcers in the stomach or first part of the small intestine (peptic ulcer); increased pressure in the eye (glaucoma) or eye problems such as clouding of the lens (cataract), or if there is a family history of glaucoma; liver problems; kidney problems.

Additional warnings

- While using the medicine, side effects typical of steroids that involve all parts of the body may appear (see section 4 "Side effects").
- Tell the 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 shingles (herpes zoster), especially if you have never had them, as exposure can cause you harm and could be life-threatening. If you do come into contact with chickenpox or shingles, **refer to the doctor immediately** (even if exposure occurs within 3 months after completing treatment).

- Tell the doctor if you have never had measles.
- If you need to be vaccinated with any vaccine during the treatment period, consult the doctor first.
- If you know that you are due to have an operation, tell the doctor that you are using **Budeson 4 mg suppositories**.
- Contact the doctor if you experience blurred vision or other visual disturbances.

Tests and follow-up

The use of **Budeson 4 mg suppositories** could affect the results of certain tests performed by your doctor or in the hospital. Tell your doctor that you are using **Budeson 4 mg suppositories** before any tests are carried out.

Elderly

Elderly patients should be monitored more closely for side effects, as they occur more frequently in this population.

Children and adolescents

Do not use the medicine in children and adolescents under 18 years of age. The efficacy and safety of this medicine have not been proven in children and adolescents under 18 years of age.

Patients with impaired liver function

Do not use this medicine in patients who have liver cirrhosis (see “*Do not use the medicine if:*” above). In patients with liver diseases that are not accompanied by cirrhosis or with slightly impaired liver function, no special dosage adjustment is required.

Patients with impaired kidney function

Caution is needed when administering the medicine to patients with severe kidney function impairment.

In patients with mild to moderate kidney function impairment, no special dosage adjustment is required.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Cardiac glycosides, such as digoxin (medicines used to treat heart conditions).
- Diuretics (to remove excess fluid from the body) – concomitant use with glucocorticoids can lead to an enhanced excretion of potassium and worsening of hypokalemia (low potassium in the blood).
- Ketoconazole or itraconazole (for treatment of fungal infection) – concomitant use with budesonide can lead to a significant increase in its plasma concentration. The combination should be avoided.
- Clarithromycin, an antibiotic for treatment of infections – concomitant use with budesonide can lead to a significant increase in its plasma concentration. The combination should be avoided.
- Carbamazepine (for treatment of epilepsy) and rifampicin (for treatment of tuberculosis) – might reduce the systemic and the local exposure of budesonide in the gut mucosa. An adjustment of the budesonide dose might be necessary.
- Estrogens or oral contraceptives.

Some medicines may increase the effect of **Budeson 4 mg suppositories** and the doctor may want to monitor you carefully if you are taking these medicines during treatment (including some medicines for HIV: ritonavir, cobicistat).

Use of the medicine and food

Avoid drinking grapefruit juice while using the medicine, as this may alter the effect of the medicine.

Pregnancy and breastfeeding

- If you are pregnant, think you are pregnant, are planning a pregnancy or breastfeeding, consult the doctor before using the medicine.
- Do not use the medicine during pregnancy unless the doctor has specifically advised that it is necessary for compelling reasons.
- Budesonide passes into breast milk. If you are breastfeeding, you should only use **Budeson 4 mg suppositories** if the doctor has instructed you to do so after taking into account the benefit of breastfeeding for the child and the benefit of therapy for the mother.

Driving and use of machinery

Using this medicine is not expected to affect or has negligible effect on your ability to drive or operate machinery.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen. The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is: one suppository once daily.

Do not exceed the recommended dose.

Duration of treatment

The doctor will decide how long you need to continue the treatment with this medicine. This will depend on your condition.

Acute episodes of ulcerative proctitis, which is an inflammation of the rectum causing ulceration and bleeding, generally subside after 6-8 weeks.

Method of administration

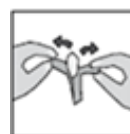
This medicine may only be used rectally, so it has to be inserted through the anus.

Do not take it by mouth.

Budeson 4 mg suppositories should be administered at bedtime, so the suppository remains in place for as long as possible.

How to insert the suppository?

- If possible, insert the suppository after bowel movement.
- Wash your hands thoroughly.
- Carefully remove the suppository from the strip just before use.



- Warming the suppository shortly beforehand with the palms of your hands may make insertion easier.



- Hold the suppository between the thumb and index finger.



- Lie down on your side in a comfortable position.



- Insert the suppository gently and deeply into the back passage (rectum), with the pointed side first.



- Wash your hands thoroughly again.

If you have accidentally taken a higher dosage

If you have used too many suppositories on one occasion, use your next dose as prescribed. Do not use a smaller amount. Contact the doctor for consultation if you are not sure what to do. Take the package of the medicine and the leaflet with you, if possible.

If a child has accidentally swallowed this medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to use the medicine at the required time, just continue your treatment and take the next dose as usual. Do not use a double dose to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor. Even if your health improves, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Consult the doctor if you want to interrupt or end your treatment early. Keep using the medicine until the doctor tells you to stop, even if you start to feel better.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using **Budeson 4 mg suppositories** may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.

The following side effects have been reported during the use of **Budeson 4 mg suppositories**:

Very common side effects (occur in more than one user out of ten):

- A decrease in cortisol hormone level in the blood.

Uncommon side effects (occur in 1-10 users out of 1,000):

- Reduced function of the adrenal glands (small glands next to the kidneys); headache; flushing; abdominal pain, flatulence, severe abdominal pain because of an acute inflammation of the pancreas; rash; changes to menstrual periods such as irregular periods.

The following side effects have been reported and are typical with medicines similar to **Budeson 4 mg suppositories** (corticosteroids), and can therefore also occur with this medicine. The frequency of these side effects is currently not known:

- Increased risk of infection.
- Cushing's syndrome, which is associated with too much corticosteroid and causes roundness of the face (swelling of the face), weight gain, high blood sugar (hyperglycemia), build-up of fluid in the tissues (edema manifested by swollen legs, for example), reduced potassium level in the blood (hypokalemia), unwanted body hair in women, impotence (inability to get or keep an erection), stretch marks on the skin, acne.
- Mood changes, such as depression, irritability or euphoria.
- Restlessness with increased physical (motor) activity, anxiety, aggression.
- Glaucoma, cataract, blurred vision.
- Increased risk of blood clots, inflammation of the blood vessels, high blood pressure.
- Dyspepsia, ulcers in the stomach and small intestine, constipation.
- Allergic skin rash, red spots from bleeding in the skin, delayed wound healing, skin reactions such as contact dermatitis, bruising.
- Muscle and joint pain, muscle weakness, muscle twitching.
- Weakening of the bones (osteoporosis), bone damage due to poor circulation of blood (osteonecrosis).
- Tiredness and general feeling of being ill.

These side effects are typical of steroid medication. They may occur depending on the 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 stronger cortisone preparations before starting treatment with **Budeson 4 mg suppositories**, disease symptoms may reappear when changing the medicines. If this happens, refer to the doctor.

Due to its local action, the risk of systemic side effects with this medicine is generally lower than when taking systemically acting glucocorticosteroids (affecting the whole body).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage <http://www.health.gov.il/>, which leads to the online form for reporting side effects, or via the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** do not store at a temperature above 25°C. Store in the original package and protect from light.
- Do not discard medicines via wastewater or household waste. Consult the pharmacist on how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Hard fat [e.g. Witepsol® H15], ascorbyl palmitate.

What the medicine looks like and what the package contains

Budeson 4 mg suppositories are white, torpedo-shaped suppositories (approximately 2 cm length) with a smooth surface.

Each pack contains 12, 30 or 60 suppositories.

Not all pack sizes may be marketed.

Manufacturer: Dr. Falk Pharma GmbH, 5 Leinenweberstrasse, Freiburg im Breisgau 79108, Germany.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301, Israel.

Medicine registration number in the national medicines registry of the Ministry of Health: 179-49-37926-99

Approved in August 2025.