

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Budeson[®] rectal foam

Active ingredient:

Each dose of *Budeson rectal foam* contains: 2 mg budesonide.

For the list of the additional ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read the entire leaflet carefully before using the medicine.

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

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems that their medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is indicated for the treatment of active ulcerative colitis that is limited to the rectum and the sigmoid colon.

Therapeutic group: anti-inflammatory corticosteroidal medicine with local activity in the intestine.

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 the additional ingredients, see section 6).
- You are suffering from a severe liver disease (liver cirrhosis).

Special warnings regarding the use of the medicine:

Before (and during) the treatment with *Budeson rectal foam*, tell the 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 the eye (glaucoma) or eye problems such as clouding of the lens (cataracts) or if glaucoma has been diagnosed in your family.
- Severe liver problems.

Additional warnings

- When using the medicine, typical side effects of steroids may occur which may affect all parts of the body, particularly if you use the medicine at high doses and for prolonged periods. See section 4. 'Side effects'.
- Tell the doctor if you have an infection during the treatment. In some cases, the infection symptoms may be atypical or less pronounced.
- Keep away from people who have chickenpox or shingles (herpes zoster), especially if you have never had them, as the exposure may harm you or even be life-threatening. If you do come into contact with chickenpox or shingles, **refer to the doctor immediately** (also if you are exposed during a period of 3 months after the end of the treatment).
- Tell the doctor if you have not yet had measles.
- If you know that you need to be vaccinated during the period of treatment, consult the doctor first.
- If you know that you are due to have an operation, tell the doctor that you are using *Budeson rectal foam*.

- If you have been treated with stronger cortisone preparations prior to starting the treatment with *Budeson rectal foam*, the symptoms may reappear when the medicine is changed. If this happens, refer to the doctor.
- Refer to the doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

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

Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines, please consult with the doctor or pharmacist):

- Systemic steroids.
- Cardiac glycosides such as digoxin (medicines used to treat heart conditions).
- Diuretics (to remove excess fluid from the body).
- Strong CYP3A4 enzyme inhibitors such as:
 - Ketoconazole or itraconazole (to treat fungal infections)
 - Antibiotic medicines to treat bacterial infections, such as clarithromycin
 - Rifampicin (to treat tuberculosis).
- Strong CYP3A4 enzyme inducers such as carbamazepine (to treat epilepsy).
- Estrogens or oral contraceptives.

Some medicines may increase the effects of *Budeson rectal foam*, and the doctor may wish to monitor your condition more closely if you are taking these medicines concomitantly (including some medicines for HIV: ritonavir, cobicistat).

Laboratory tests

Budeson rectal foam could affect the results of some tests carried out by your doctor or in the hospital. Tell your doctor that you are using *Budeson rectal foam* before any tests are carried out.

Use of the medicine and food

Do not drink grapefruit juice during the treatment, as this can alter the effect of the medicine.

Pregnancy and breastfeeding

If you are pregnant, think you are pregnant, are planning a pregnancy or are breastfeeding, consult the doctor before using the medicine.

Do not use *Budeson rectal foam* during pregnancy, unless explicitly instructed to do so by the doctor. Budesonide passes into the breast milk. Do not use *Budeson rectal foam* if you are breastfeeding, unless explicitly instructed to do so by the doctor. You should consult the doctor about the benefits of breastfeeding for the infant versus the benefit of the treatment for the mother.

Driving and use of machinery

The use of the medicine is not expected to affect your ability to drive or operate machinery.

Important information about some of the medicine's ingredients

- *Budeson rectal foam* contains 600.3 mg propylene glycol in each actuation. Propylene glycol may cause skin irritation.
- The medicine contains cetyl alcohol and cetostearyl alcohol (component of emulsifying wax), which may cause local skin reactions (e.g., contact dermatitis).

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 regarding the dosage and treatment regimen.

The dosage, duration of treatment and treatment regimen will be determined by the doctor only.

The standard dosage is usually:

Adults over 18 years of age: one spray actuation per day, either in the morning or at bedtime.

Emptying your bowels before using *Budeson rectal foam* will produce the best results.

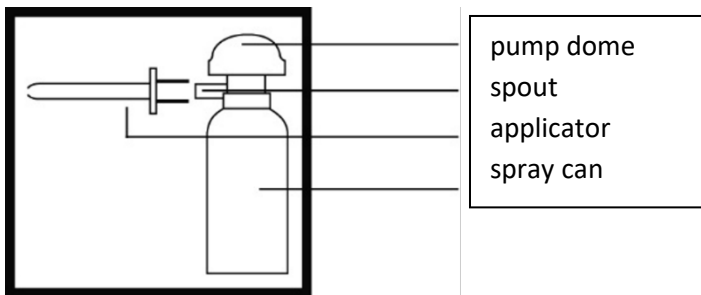
Do not exceed the recommended dosage.

Method of administration:

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

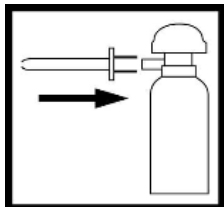
The medicine is not intended to be taken by mouth. Do not swallow.

Picture of the spray can

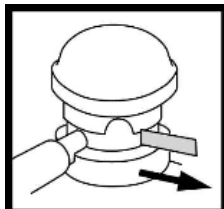


The applicators are in a special rail. Hold the rail firmly and pull the applicator out sharply.

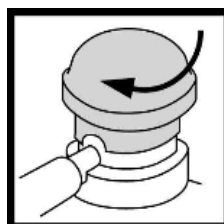
Preparing to use the foam



Push the applicator firmly onto the spout of the spray can. Shake the spray can for about 15 seconds to mix the contents.

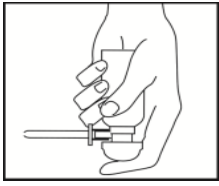


Before the first use, remove the safety lock (plastic flap) from under the pump dome.

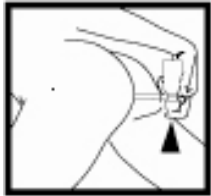


Twist the dome on the top of the spray can until the semi-circular gap underneath is in line with the applicator. The spray can is now ready for use.

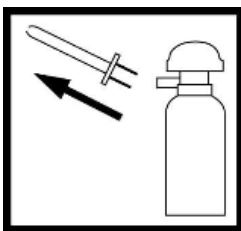
Using the foam



Place your index finger on the top of the pump dome and turn the can upside down. Note that the spray can will only work properly when held with the pump dome pointing down as vertically as possible.



Stand with one foot on a stool or chair or lie on your side with the lower leg stretched out and the upper leg bent for balance. Insert the applicator into your rectum as far as possible. Push the pump dome down fully once and then slowly release it – the foam comes out of the spray can when you release the dome. Keep the applicator in place for 10 - 15 seconds before taking it out. This ensures the full dose is delivered into the rectum and no foam is spilled.



After administering the foam, remove the applicator and dispose of it with your household waste in the plastic bag provided. Use a new applicator for the next application.

In order to prevent the inadvertent loss of foam from the spray can between applications, turn the pump dome around so that the semi-circular gap faces the opposite direction to the spout.

- Wash your hands and try not to empty your bowels until the next morning.
- If you refer to a hospital or another doctor or dentist, tell them you are using this medicine.

Duration of treatment:

The duration of the treatment with the medicine depends on your condition. The doctor will decide how long you must continue to use the medicine.

Acute episodes of inflammatory bowel disease (ulcerative colitis) generally subside after 6 - 8 weeks.

If you think that the effect of *Budeson rectal foam* is too strong or too weak, talk to the doctor.

If you accidentally used a higher dosage

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

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

If you forgot to take the medicine

If you missed a dose, just continue your treatment at the prescribed dosage. Do not use a double dose to compensate for the forgotten dose.

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

If you stop using the medicine

Consult the doctor if you want to interrupt or end your treatment early. Do not stop using the medicine abruptly as it could make you ill. Keep using the medicine until the doctor tells you to stop, even if you start to feel better.

Do not take or use 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 concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of this preparation may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Refer to the doctor immediately if you get one or more of the following symptoms, after using the medicine:

- Infection
- Headache
- Changes in behavior such as depression, irritability, euphoria, restlessness, anxiety or aggression.

Additional side effects:

Common side effects (appear in 1-10 users out of 100):

- Burning or pain in the rectum.
- Cushing's syndrome, manifested by roundness of the face, weight gain, reduced glucose tolerance, high blood sugar, high blood pressure, fluid retention in the tissues (e.g., swollen legs [edema]), increased excretion of potassium (hypokalemia), 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 bowel.
- Increased risk of infections.
- 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 side effects (appear in 1-10 users out of 1,000):

- An increase in appetite.
- Changes to the blood (increase in erythrocyte sedimentation rate, increase in the number of white blood cells).
- Nausea, abdominal pain, wind, tingling or numbness in the abdomen, anal fissure, mouth ulcers, frequent need to empty the bowels, rectal bleeding.
- Ulcers in the stomach or small intestine.
- Changes in liver function parameters.
- Changes in pancreatic function, changes in adrenal hormones.
- Urinary tract infections.
- Giddiness, disturbance of smell.
- Sleeplessness, restlessness with increased physical activity, anxiety.
- Increased sweating, weakness.

Rare side effects (appear in 1-10 users out of 10,000):

- Blurred vision.
- Inflammation of the pancreas.
- Bone loss due to poor circulation of blood (osteonecrosis).
- Aggression.
- Bruising (subdermal hematoma).

Very rare side effects (appear in less than 1 user out of 10,000):

- 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 clot formation, inflammation of the blood vessels (associated with stopping use of cortisone [steroids] after long-term therapy).
- Tiredness, general feeling of being ill.

The side effects listed above are typical of steroid medication and most of them can also be expected for treatments with other steroids. They may occur depending on the dose, duration of treatment, use of other cortisone preparations in the past or concurrently, and your individual susceptibility.

Some of these unwanted effects were only reported after long-term use of oral budesonide.

In general, the risk of side effects with *Budeson rectal foam* is lower than with systemically acting (affecting the whole body) cortisone preparations due to its local action.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il), which leads to an online form for reporting side effects, or by entering 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 safe place out of the sight and reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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.
- Use the contents of the container within 4 weeks after the first opening.
- **Storage conditions:** protect from sunlight, store below 25°C. Do not refrigerate or freeze.
- The container is pressurized and contains flammable propellant. Do not expose to temperature higher than 50°C. Protect from direct sunlight. Do not pierce or burn, even when empty.

6. Additional information

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

Propylene glycol, purified water, emulsifying wax (Polawax®)*, macrogol stearyl ether (Brij®76), cetyl alcohol, citric acid monohydrate, disodium edetate, propane, n-butane, isobutane, nitrogen.

* cetostearyl alcohol, polysorbate 60.

What does the medicine look like and what does the package contain

Budeson rectal foam is a white to pale white, creamy, firm foam and is contained in a pressurized container.

The medicine comes in a pack containing one pressurized container, 14 applicators and 14 plastic bags.

The plastic bags are intended for the hygienic disposal of the applicators.

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

Manufacturer: Dr. Falk Pharma GmbH, Freiburg, Germany.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 173 96 36576 99.

Revised in August 2024.

