Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986

This medicine is sold with a doctor's prescription only

Budeson 3 mg Capsules

Active ingredient:
Each capsule of Budeson contains: Budesonide 3 mg
For a list of the other ingredients, please see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.
Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, please refer to your 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 to you that their illness is similar to yours.

1. What is the medicine intended for?

The medicine is intended:

- For the treatment of acute mild to moderate Crohn's disease in the small intestine and/or the large intestine.
- For the treatment of collagenous inflammation of the large intestine (Collagenous colitis).
- For the treatment of autoimmune inflammation of the liver (Autoimmune hepatitis).

Therapeutic group: Steroidal (glucocorticosteroidal) anti-inflammatory medicine with local activity.

2. Before you take the medicine

Do not use this medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).
- Do not use if you suffer from liver cirrhosis.

Special warnings regarding the use of this medicine:

- Do not use this medicine frequently or for a prolonged period without consulting your doctor.
- During the use of the medicine, typical steroidal side effects may occur. It may occur especially if you are taking the medicine at a high dosage or for a prolonged period. Please see section 'Side effects'.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Inform your doctor if you are about to undergo surgery during the treatment period with Budeson.
- Inform your doctor if you have been injured or bruised during the treatment.
- Refer to your doctor if during treatment, you suffer from an infection (i.e. parasitic, fungal, bacterial or viral). The symptoms of the infection may be atypical, so refer to your doctor in any case where infection is suspected.
- Avoid being exposed to patients with shingles (herpes zoster), measles or chickenpox (especially if you have never contracted these diseases before). In

case you have been exposed, refer to your doctor (also up to a 3 months period after the end of treatment).
- Consult your doctor if you need to be vaccinated with any type of vaccine during the treatment period.
- If you have been treated with other steroidal medicines before starting treatment with Budeson, the symptoms of the disease may recur when switching between the medicines. If this occurs - refer to your doctor.
- Inform your doctor about taking the medicine before undergoing tests, since Budeson may affect certain test results.
- If you are sensitive to any type of food or medicine, inform your doctor before taking this medicine.

Before starting the treatment with Budeson tell your doctor:
- If you suffer or have suffered in the past from impaired function of the: eyes (e.g. glaucoma or cataract), liver, immune system.
- If you suffer or have suffered in the past from tuberculosis, high blood pressure, diabetes, ulcers in the stomach or the intestine, osteoporosis.
- If you suffer from infection (i.e. parasitic, fungal, bacterial or viral).
- If one of your family members has been diagnosed with diabetes or glaucoma.
- If you have never contracted measles.

Use in children and adolescent:
- Children: the medicine should not be used in children younger than 12 years of age due to insufficient information on the use of this medicine in this age group and there is a risk of adrenal suppression.
- Adolescents: the information regarding usage in the age range of 12 to 18 years is limited.

Tests and follow up: liver tests and liver function tests are recommended for patients with autoimmune hepatitis.

Drug interactions:
If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using any of these medicines, please consult with your doctor or pharmacist):
- Other systemic steroids.
- Cardiac glycosides (e.g. digoxin for the treatment of heart problems).
- Diuretics and medicines that increase salt excretion in the urine.
- Ketoconazole, itraconazole (for the treatment of fungal infections).
- Antibiotics such as clarithromycin or rifampicin.
- Carbamazepine (for the treatment of epilepsy).
- Estrogens or birth control pills.
- Cimetidine (for the treatment of heartburn and stomach ulcer).
- Cholestyramine, antacids: wait at least two hours between taking Budeson and taking these medicines.

- Some medicines may increase the effect of Budeson and your doctor may wish to monitor your condition, if you are taking these medicines concomitantly with Budeson. These medicines include, amongst others, some medicines for treating AIDS/against the HIV virus: ritonavir, cobicistat.

Use of this medicine and food:

- Take this medicine about half an hour before a meal (also see section 'How to use this medicine?')
- Avoid eating grapefruits or drinking grapefruit juice during the treatment period.

Pregnancy and breastfeeding:

Do not use the medicine without consulting your doctor if you are pregnant, think you are pregnant, planning a pregnancy, or are breastfeeding.

- The use of Budeson should be avoided during pregnancy, unless explicitly instructed so by the doctor.
- Budeson passes into breast milk and therefore do not breastfeed during the treatment period with this medicine.

Driving and operating machinery:

The use of the medicine is usually not expected to affect your ability to drive or to operate machinery. Either way, do not drive if you feel symptoms which may affect this ability.

Important information about some of the medicine's ingredients:

Each capsule contains approximately 12 mg lactose and 240-276 mg sucrose (a type of sugar). If you are sensitive to lactose, or if you have an intolerance to some sugars, inform your doctor before taking this medicine.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment.
The dosage, treatment duration and manner of treatment will be determined by the doctor only.
The medicine should be taken at set intervals as determined by the attending doctor.

The standard dosage, unless your doctor instructs you otherwise, is usually:
For the treatment of Crohn's disease (adults over 18 years of age):
Three capsules a day (24 hours).
The medicine can be taken three times a day, one capsule each time, about half an hour before a meal, or the three capsules can be taken together at one time, about half an hour before breakfast.
The duration of the treatment is usually 8 weeks. The full effect is usually achieved after 2 to 4 weeks.

For the treatment of collagenous colitis (adults over 18 years of age):
Three capsules together once daily about half an hour before breakfast.
The duration of the treatment is usually 8 weeks. The full effect is usually achieved after 2 to 4 weeks.

For the treatment of autoimmune hepatitis (adults over 18 years of age):

- For the treatment of an active inflammation: one capsule, three times a day.
- For maintenance treatment: one capsule, twice a day.

The duration of the treatment and the dose will be determined by your doctor.

Do not exceed the recommended dose.
The medicine is intended for oral use only.
Take this medicine about half an hour before a meal with a glass of water.
Swallow the capsules whole. Do not chew the capsules since it may impair the activity of the medicine.
Patients who have difficulty swallowing capsules - the capsule may be opened and its content may be swallowed with water. Do not chew the granules.
If you are taking antacids or resins such as cholestyramine, wait at least 2 hours between taking Budeson and taking these medicines.

If you have accidentally taken a higher dosage:
If in a certain case you have taken a higher dose, take the next dose as directed by your doctor. Refer to your doctor if you are not sure what to do.
If you have taken an overdose or 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 this medicine at the set time, take a dose as soon as you remember. If you miss a dose, take the next dose as usual. Do not take a double dose to make up for the forgotten dose.

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

If you stop taking the medicine:
Consult your doctor if you want to stop taking the medicine before completion of the treatment period determined by the doctor. Do not stop taking this medicine abruptly. Discontinuation of the medicine will usually be done gradually, and according to your doctor's instructions.

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 any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:
Like any medicine, the use of Budeson 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 a doctor immediately if one or more of the following symptoms occur (see frequency in the list below):
- Infection.
- Headache.
- Blurred vision or other visual disturbances.
- Psychiatric effects or changes in behaviour and mood, such as: depression, nervousness/irritability, euphoria, restlessness, anxiety or aggression.

Additional side effects:

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

- Cushing's syndrome manifested by swollen face (round face), weight gain, decrease in glucose tolerance and increase in blood sugar levels/diabetes, high blood pressure, fluid and sodium retention (edema manifested for instance by swelling of the legs), excessive potassium excretion (hypokalemia); hormonal disturbances such as menstrual disorders in women, excess hair growth in women, impotence; decrease in (including lack of) adrenal function (expressed in blood tests); red stripes on the skin (stretch marks), acne.
- Disorders of the digestive system.
- Increased risk of infection.
- Muscle and joint pain, muscle weakness, muscle twitching.
- Osteoporosis.
- Headache.
- Mood changes such as depression, irritability /nervousness or euphoria.
- Rash as a result of a hypersensitivity reaction, bleeding spots in the skin, delayed wound healing, local skin reactions such as skin inflammation from contact (contact dermatitis).

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

- Ulcers in the stomach or small intestine.
- Restlessness accompanied by increased motor activity, anxiety.

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

- Blurred vision, glaucoma (increased pressure in the eye), cataract (clouding of the eye lens).
- Inflammation of the pancreas.
- Bone necrosis (osteonecrosis).
- Aggression.
- Bruising, haemorrhages (bleeding) under the skin.

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

- Slowed growth in children.
- Constipation.
- Increased pressure in the brain, sometimes accompanied by increased pressure in the eye in adolescents.
- Increased risk of the formation of blood clots, inflammation of blood vessels.
- Tiredness, feeling ill and generally unwell.

The side effects of Budeson are typical for steroidal medicines, and are affected by the dose, the duration of the treatment, the use of other steroidal medicines and your sensitivity to the treatment.
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 your 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 you to the online form for reporting side effects, or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic
@moh.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 unless explicitly instructed to do so by a 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: Store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sucrose, gelatin, maize starch, talc, ammonio methacrylate copolymer (eudragit), lactose monohydrate, purified water, triethyl citrate, titanium dioxide (E171), povidone K25, red ferric oxide (E172), erythrosine (E127), black ferric oxide (E172), sodium lauryl sulphate.

What does the medicine look like and what does the package contain?
Pink capsules which contain white granules, in blister packs. Each package contains 100 capsules.

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.
Manufacturer: Dr. Falk Pharma GmbH, Freiburg, Germany.
Medicine registration number in the National Medicine Registry of the Ministry of Health: 104 52 28653

This leaflet was checked and approved by the Ministry of Health in May 2016, and was updated according to the guidelines of the Ministry of Health in January 2019.

291007-F