Package leaflet: Information for the patient

Budesonide Teva
3 mg Gastro-resistant Capsules, Hard
budesonide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Budesonide Teva is and what it is used for
2. What you need to know before you take Budesonide Teva
3. How to take Budesonide Teva
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1. What Budesonide Teva is and what it is used for

Budesonide Teva Gastro-resistant Capsules contain the active substance budesonide, a type of locally acting steroid used to treat chronic inflammatory diseases of the intestine and the liver.

Budesonide Teva are 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 Budesonide Teva

Do NOT take Budesonide Teva:
- if you are **allergic** to budesonide or any of the other ingredients of this medicine (listed in section 6)
- if you have a **severe liver disease** (liver cirrhosis).

Warnings and precautions
Talk to your doctor or pharmacist before taking budesonide 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.

Budesonide Teva Gastro-resistant Capsules are not suitable for patients with Crohn's disease affecting the upper gastrointestinal tract.

Sometimes this disease may cause symptoms outside the intestine (e.g. affecting the skin, eyes and joints) which are unlikely to respond to this medicine.

Typical effects of cortisone preparations may occur, which may affect all parts of the body, particularly when you take budesonide at high doses and for prolonged periods (see section 4. Possible side effects).

Further precautions during treatment with Budesonide Teva:
- Tell your doctor if you have an infection. The symptoms of some infections can be unusual or less pronounced.
- 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 budesonide.
- If you have been treated with a stronger cortisone preparation before starting treatment with budesonide, your symptoms may reappear when the medicine is changed. If this happens, contact your doctor.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- If you have autoimmune hepatitis, your doctor will carry out liver function tests regularly and will adjust the dosage of this medicine periodically.

Other medicines and Budesonide Teva
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular:
- **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** drugs used to treat infections (such as clarithromycin)
- **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 Budesonide Teva 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 **colestyramine** (for hypercholesterolemia and also used to treat diarrhoea) or **antacids** (for indigestion) in addition to Budesonide Teva, take these medicines **at least 2 hours apart**.

Budesonide Teva could affect the results of tests performed by your doctor or in hospital. Tell your doctor that you are taking Budesonide Teva before any tests are carried out.

Budesonide Teva with food and drink
You should **not** drink **grapefruit juice** whilst you are taking this medicine as this can alter its effects.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
You should only take Budesonide Teva during pregnancy if your doctor tells you to.

Budesonide Teva passes, in small amounts, into breast milk. If you are breast-feeding you should only take Budesonide Teva if your doctor tells you to.

Driving and using machines
Budesonide Teva Gastro-resistant capsules are not expected to affect your ability to drive or operate machinery.

Budesonide Teva contains sucrose and sodium
Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say it is essentially 'sodium-free'.

3. How to take Budesonide Teva

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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 your 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 Budesonide Teva 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.

Use in children (all indications)
Budesonide Teva Gastro-resistant Capsules should NOT be used in children under 12 years of age. There is only limited experience with the use of budesonide capsules in children older than 12 years of age.

Method of administration
Budesonide Teva Gastro-resistant 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.

If you take more Budesonide Teva than you should
If you have taken too much medicine on one occasion, take your next dose as prescribed. Do not take a smaller amount. Contact a doctor if you are in doubt so he or she can decide what to do; take the carton and this leaflet with you if possible.

If you forget to take Budesonide Teva
If you miss a dose, just continue your treatment at the prescribed dosage. Do NOT take a double dose to make up for a forgotten dose.

If you stop taking Budesonide Teva
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 over a course of two weeks.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following symptoms after taking this medicine, you should contact your doctor immediately:
- infection
- headache
- changes in behaviour such as depression, irritability, euphoria, restlessness, anxiety or aggression.

The following side effects have also been reported:

Common: may affect up to 1 in 10 people
- Cushing's syndrome – e.g. with roundness of the face, weight gain, reduced glucose tolerance, high blood sugar, high blood pressure, fluid retention in the tissues (e.g. swollen legs), increased excretion of potassium (hypokalaemia), 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 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.

Uncommon: may affect up to 1 in 100 people
- ulcers in the stomach or small intestine
- restlessness with increased physical activity, anxiety.

Rare: may affect up to 1 in 1,000 people
- blurred vision
- inflammation of the pancreas
- bone loss due to poor circulation of blood (osteonecrosis)
- aggression
- bruising.

Very rare: may affect up to 1 in 10,000 people
- 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 medication 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 Budesonide Teva Gastro-resistant Capsules, your symptoms may reappear when the medicine is changed.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Budesonide Teva

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the blister, carton or bottle after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Budesonide Teva contains
- The active substance is budesonide. Each capsule contains 3 mg of budesonide.
- The other ingredients are:
  - *Capsule content:* Sugar spheres (sucrose, corn starch), Opadry QX (macrogol poly(vinyl alcohol) grafted copolymer, talc, glycerol monocaprylocaprate (type I), poly(vinyl alcohol)), methacrylic acid - methyl methacrylate copolymer (1:1), methacrylic acid - methyl methacrylate copolymer (1:2), ammonio methacrylate copolymer (type B), ammonio methacrylate copolymer (type A), triethylcitrate, talc
  - *Capsule shell:* Brilliant blue FCF (E133), quinoline yellow (E104), erythrosine (E127), titanium dioxide (E171), sodium laurilsulfate, gelatin

What Budesonide Teva looks like and contents of the pack
Budesonide Teva Gastro-resistant Capsules are amethyst and opaque capsules filled with white pellets.

Budesonide Teva is available in unit-dose blisters containing 20, 50, 60, 90, 100 or 120 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer
Balkanpharma-Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa, 2600, Bulgaria

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Other sources of information
To request a copy of this leaflet in braille, large print or audio please contact:
Email: medinfo@tevauk.com,
Telephone: +44 (0)207 540 7117
Please provide the following information:
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