Package leaflet: Information for the user

Budaxiro 3 mg modified-release capsule, 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 <invented name> is and what it is used for
2. What you need to know before you take <invented name>
3. How to take <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

1. What <invented name> is and what it is used for

<*invented name*> reduce inflammation in the small intestine and the first part of the large intestine.

<*invented name*> is used to treat Crohn's disease of the small intestine and the first part of the large intestine. Crohn's disease is an inflammatory disease of the bowel that causes symptoms in the form of diarrhoea, fever and stomach pain.

<*invented name*> is used to treat microscopic colitis, which is a disease producing chronic inflammation of the colon and often resulting in watery diarrhoea. <*invented name*> can be used to treat both active illness as well as in severe cases to prevent recurring problems (maintenance treatment).

2. What you need to know before you take <invented name>

Do not take <invented name>
- if you are allergic to budesonide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking <invented name> if:
- bacterial, fungal or viral infection
- any liver disease
- osteoporosis
- gastric ulcer
- hypertension
- diabetes (also applicable if there is any family history of diabetes)
- any eye disease (also applicable if there is any family history of eye disease)

Measles and chickenpox can be more troublesome when you take <invented name>. So, if you are/become infected, contact a doctor.

Contact your doctor if you experience blurred vision or other visual disturbances.

When you switch from regular cortisone tablets to <invented name> or when you stop taking <invented name>, you may temporarily display symptoms such as rash, runny nose and muscle aches. Should you experience any of the foregoing or be troubled by headache, tiredness or nausea, then consult a doctor.

If you are going to have surgery, you should tell your doctor that you are taking <invented name>, as you may need to supplement with regular cortisone tablets for a while.

Children and young people
Regular monitoring of height growth is recommended for children and adolescents being treated with <invented name>.

Other medicines and <invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect or be affected by treatment with <invented name>, for example:
- certain medicines prescribed for fungal infections (e.g., itraconazole)
- medicines used to treat Cushing's syndrome - when the body produces an excess of cortisol (ketoconazole tablets)
- medicines for menopausal symptoms (oestrogens) and pregnancy (birth control pills)
- carbamazepine (for epilepsy)
- certain medicines may increase the effects of <invented name>, and your doctor may need to monitor your treatment closely if you are taking these medicines (e.g., certain prescriptions for the treatment of HIV: ritonavir (or other HIV protease inhibitors), cobicistat).

<invented name>, may affect a test carried out to check the function of the pituitary gland – the so-called the ACTH stimulation test – resulting in the test giving incorrectly low values.

<invented name> with food and drink
The intake of grapefruit juice should be avoided during treatment with <*invented name*>, as grapefruit may increase the uptake of budesonide from the intestine (juices of other fruits such as apple or orange do not affect the uptake of budesonide).

Pregnancy, breast-feeding and fertility
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.

There is a risk of the foetus being affected. Therefore, always consult your doctor before using <*invented name*> if you are pregnant.

Budesonide passes into breast milk. Therefore, talk to your doctor before using <*invented name*> regularly during breast-feeding.

Driving and using machines
<invented name> are not likely to affect you being able to drive or use any machines.

<invented name> contain Sugar spheres (maize starch, sucrose)
<invented name> contain sucrose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

<invented name> contain Potassium

<invented name> contains potassium. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

This medicine contains potassium, less than 1 mmol (39 mg) per, i.e. essentially 'potassium-free'.

3. How to take <invented name>

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 capsules should be swallowed whole with water.
The capsules must not be chewed or crushed.
If you have difficulty swallowing, you can open the capsule and swallow the contents mixed with a tablespoon of apple puree. The contents must not be broken into pieces or chewed.

Crohn's disease:

Recommended dosage for adults and children over 8 years with a body weight in excess of 25 kg:
For treatment of the active disease: 3 modified release capsules (i.e. 9 mg budesonide) in the morning for 8 weeks. It may take between 2 and 4 weeks before <*invented name*> takes its full effect.

Do not forget to take the modified release capsules even if you feel better.
Treatment should be stopped by gradually reducing the dosage.

Microscopic colitis:

Recommended dosage for adults:
For treatment of the active disease: 3 modified release capsules (i.e 9 mg budesonide) in the morning for 8 weeks. When the time arrives to end the treatment, the dosage should be steadily reduced over the course of the final two weeks.
Maintenance treatment: 2 capsules (i.e 6 mg budesonide) (or the lowest effective dose).

Use in children
The recommend dose for children over 8 years with a body weight in excess of 25 kg for Crhon's disease is 3 modified release capsules (i.e. 9 mg budesonide) in the morning for 8 weeks.

If you take more <invented name> than you should
If you take more <invented name> than you should, talk to a doctor or pharmacist straight away.

If you forget to take <invented name>
Do not take a double dose to make up for the dose that you missed. Just continue with the next dose according to the schedule originally prescribed by your doctor.

If you stop taking <invented name>
Do not stop taking <invented name> without talking to your doctor first. If you stop taking your capsules suddenly it may make you ill.

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.

The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)
- low blood potassium content
- behavioural changes such as nervousness, insomnia, mood swings and depression
- abnormally fast or irregular heartbeat
- indigestion (dyspepsia)
- hives and rashes
- muscle cramps
- menstrual disorders
- fat deposits on the torso and face, skin changes, fluid accumulation in the body (so-called Cushing-like symptom picture).

Uncommon (may affect up to 1 in 100 people)
- tremors
- restlessness, strong drive to be physically active with concomitant mental anxiety (psychomotor hyperactivity)
- anxiety

Rare (may affect up to 1 in 1000 people)
- Aggression.
- clouding of the eye's natural lens including the back of the lens, glaucoma (glaucoma), blurred vision
- bluish-purple discoloration of the skin resulting from bleeding beneath the skin.

Very Rare (may affect up to 1 in 10,000 people)
- severe allergic reactions
- growth inhibition

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 national reporting system listed in Appendix V.* By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <invented name>

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

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

If your capsules become discoloured or show any other signs of deterioration please ask your doctor or pharmacist before taking your medicine.

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.

Store in original bottle in order to protect from light and moisture.

This product does not require any special temperature storage restrictions

6. Contents of the pack and other information

What <invented name> contains
- The active substance is budesonide.
- The other ingredient(s) are:

Capsule content
Ethyl cellulose
Methacrylic acid-ethyl acrylate copolymer
Oleic acid
Polysorbate 80
Sugar spheres (maize starch, sucrose)
Talc
Triethyl citrate
Triglycerides, medium chain

Capsule shell
Black iron oxide E172
Red Iron Oxide E172
Titanium dioxide E171
Gelatin

What <invented name> looks like and contents of the pack

<invented name> are approximately 19 mm gelatine capsules, light grey opaque body and swedish orange opaque cap. The capsules are filled with white to off-white pellets.

<invented name> are available in HDPE bottles with PP screw cap including silica desiccant packsizes containing 20, 50 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer
Laboratorios LICONSA S.A.
Av. De Miralcampo 7
19200 Azuqueca de Henares
Guadalajara, Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Sweden	Budaxiro
Germany	Budaxiro 3 mg Hartkapseln mit veränderter Wirkstofffreisetzung

This leaflet was last revised in 2024-02-15