

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

- a. What Budesonide Inhaler is and what it is used for
- b. Before you use Budesonide Inhaler
- c. How to use Budesonide Inhaler
- d. Possible side effects
- e. How to store Budesonide Inhaler
- f. Further information

a) WHAT BUDESONIDE INHALER IS AND WHAT IT IS USED FOR

The active ingredient in Budesonide Inhaler is budesonide. Budesonide powder is packed in an inhaler.

You inhale the powder into your lungs through the mouthpiece of the inhaler. Budesonide works by reducing and preventing swelling and inflammation in your lungs.

Budesonide is a medicine called “preventer”. It is used to prevent symptoms of asthma. It belongs to a group of medicines called corticosteroids.

Budesonide will NOT stop an asthma attack that has already started. Therefore you always need to have a fast acting bronchodilating “reliever” (a beta2-agonist) with you.

The effect of budesonide may be noticeable after a few days treatments but will only reach its maximum after a few weeks. You should use Budesonide regularly to prevent the asthmatic inflammation.

Go on taking this medicine regularly according to instructions, even if you don’t have any symptoms.

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b) BEFORE YOU USE BUDESONIDE INHALER

Do not use Budesonide Inhaler

Do not use Budesonide, if you are allergic:

- To budesonide
- To the other ingredient of this medicine (listed in section f) which is lactose (which contains small amounts of milk protein).

Contact your doctor so that your medicine can be changed to another.

Take special care with

Tell your doctor before you use Budesonide, if you have:

- Pulmonary tuberculosis
- Any untreated bacteria, virus or fungal infections in your mouth, airways or lungs
- Severe liver disease.

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

Rinse your mouth after inhaling your dose in order to avoid fungal infection in the mouth.

Budesonide is not recommended to be used in children who are younger than 6 years.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

Some medicines may increase the effects of Budesonide and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Tell your doctor, if you are using:

- Nasal medicines containing corticosteroids
- Corticosteroid tablets
- Itraconazol or ketoconazol containing antifungal medicines.

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 for advice before taking this medicine. It is important for both foetus and mother to maintain an adequate asthma treatment during pregnancy. As with

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other drugs administered during pregnancy, the benefit of the administration of budesonide for the mother should be weighed against the risks to the foetus. The lowest effective dose of budesonide needed to maintain adequate asthma control should be used.

Driving and using machines

Budesonide is not known to affect your ability to drive or operate machinery.

Important information about some of the ingredients of budesonide inhaler

Budesonide inhalation powder contains a small amount of lactose, which probably does not cause problems even if you have lactose intolerance. If you have been told by your doctor that you have intolerance to some sugars talk to your doctor before using this medicine.

Lactose contains small amounts of milk proteins, which may cause allergic reaction.

c) HOW TO USE BUDESONIDE INHALER

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

Your doctor has prescribed a suitable strength and dose for you. Follow your doctor's instructions carefully.

Replacing corticosteroid tablets with Budesonide:

Tell your doctor, if you use corticosteroid tablets (e.g. cortisone tablets) to treat your asthma.

Your doctor may ask you to gradually reduce the number of tablets and finally stop the treatment within a few weeks. If you feel unwell during this transfer period, contact your doctor, but do not stop using Budesonide.

Use in adults (including the elderly) and adolescents (12 to 17 years):

- 1–2 doses inhaled in the mornings and in the evenings or once a day in the evenings.

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Use in children 6 to 11 years:

- 1–2 doses inhaled in the mornings and in the evenings or once a day in the evenings.

While the treatment continues your doctor may from time to time adjust the dose to find the lowest dose needed to control your asthma (the maintenance dose).

If Budesonide is to be used by your child, make sure that he/she can use it correctly.

In addition to the preventer, Budesonide, you also need a bronchodilating reliever:

Budesonide will NOT stop an asthma attack that has already started. Therefore you always need to have a fast acting bronchodilating reliever (a beta2-agonist) with you in case of acute symptoms of asthma.

If you regularly use a reliever inhaler (beta2-agonist), you should inhale it before Budesonide (preventer).

Worsening of the asthma symptoms during the treatment:

Contact your doctor as soon as possible, if:

- Your wheezing or chest tightness gets worse during the treatment
- You need to use your reliever inhaler more often than before
- Your reliever inhaler doesn't help as well as before

Your asthma may be getting worse and you may need an extra treatment.

If you use more budesonide than you should

If you have taken a larger dose or more doses than you were told to, tell your doctor as soon as possible. You should continue to use Budesonide unless your doctor tells you otherwise.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to use budesonide

If you have missed a dose, take one as soon as possible, or you can just take the next dose when it is due. It is best to take your medicine at the same time each day.

Do not take a double dose to make up for a forgotten dose.

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If you stop using budesonide

Do not stop using Budesonide without consulting your doctor. If you stop using this medicine abruptly, it may make your asthma worse.

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

d) POSSIBLE SIDE EFFECTS

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

Common (may affect up to 1 in 10 people):

Irritation in throat, swallowing difficulties, cough and fungal infection (thrush) in mouth or throat. If you get any of these side effects, do not stop taking Budesonide. Talk to your doctor.

You can help to prevent the above mentioned side effects by rinsing your mouth and throat with water or brushing your teeth after every time you have taken a dose. Do not swallow the rinsing water, spit it out.

Uncommon (may affect up to 1 in 100 people):

Anxiety, depression, cataract, blurred vision, muscle spasm and tremor.

Rare (may affect up to 1 in 1,000 people):

Too much or too little cortisol in blood. Underactive adrenal gland (gland next to kidneys). Skin rash, itching, bruising, hoarseness, restlessness and nervousness. Growth retardation in children. Behavioural changes especially in children.

Rare serious allergic reaction:

If itching, rash, reddened skin, swelling of the eye lids, lips, face or throat, wheezing, low blood pressure or collapse appear shortly after taking a dose, act in the following way:

- Stop taking Budesonide
- Seek medical advice immediately.

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Shortness of breath immediately after dosing:

Rarely, inhaled drugs can cause an increase in wheezing and shortness of breath (bronchospasm) immediately after dosing, if this occurs:

- Stop taking Budesonide
- Take fast acting bronchodilating reliever
- Seek medical advice immediately.

Very rare (may affect up to 1 in 10,000 people):

Glaucoma. Decrease in bone mineral density (weakening of the bones).

Not known (frequency cannot be estimated from the available data):

Sleeping problems, aggressiveness, increased motor activity (difficulty to stay still) and irritable. These effects are more likely to occur in children.

If you think you might have any of these rare side effects, or if you are worried about the possibility of them, talk to your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

e) HOW TO STORE BUDESONIDE INHALER

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

Before the first use: store in unopened foil bag.

After opening the foil bag: store below 30°C protected from moisture. It is recommended to keep the Budesonide inhaler in its protective cover.

Replace Budesonide with a new at the latest 6 months after you opened the foil bag.

Write down the date you opened the bag to help you remember.

If your Budesonide gets damp, you need to replace it with a new one.

Do not use this medicine after the expiry date which is stated on the label and carton.

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

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f) FURTHER INFORMATION

What budesonide inhaler contains

The active substance is budesonide

The other ingredient is lactose monohydrate (which contains milk protein)

What budesonide inhaler looks like and content of the pack

White or almost white powder

Budesonide 100 microg/dose inhalation powder

- 200 doses + protective cover
- 200 doses
- 2 x 200 doses
- 600 doses (3 x 200 doses)

Budesonide 200 microg/dose inhalation powder

- 120 doses
- 200 doses + protective cover
- 200 doses
- 2 x 200 doses
- 600 doses (3 x 200 doses)

Budesonide 400 microg/dose inhalation powder

- 100 doses + protective cover
- 100 doses
- 2 x 100 doses
- 3 x 100 doses

Not all pack sizes may be marketed.

Supplier

Macleods Pharmaceuticals Ltd.
304, Atlanta Arcade,
Marol Church Road,
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Manufacturer

**Macleods Pharmaceuticals
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Reference:

<https://www.medicines.org.uk/emc/product/242/pil>