

PULVISIONIDE INHALATION CAPSULE 200 MCG

Budesonide (200 mcg)

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What PULVISIONIDE is used for

PULVISIONIDE is used for the regular treatment of asthma.

How PULVISIONIDE works

PULVISIONIDE relieves and prevents inflammation in the airways caused by asthma.

PULVISIONIDE is intended for regular use and not for rapid relief of acute asthma conditions. It may take some weeks before you receive the full effect of the treatment.

Before you use PULVISIONIDE

- When you must not use it

Do not use PULVISIONIDE if you were allergic (hypersensitive) to budesonide or any of its excipient.

- Before you start to use it

If you switch from cortisone tablets to PULVISIONIDE as your previous allergic symptoms such as a runny nose and eczema may return in certain cases. You may also experience tiredness, headaches, muscle and joint pain and occasionally nausea and vomiting. This is because the total amount of cortisone in the body is reduced when the disease is treated locally in the lungs. These symptoms disappear after you have received treatment for some time.

It is important that you tell your doctor if you have impaired liver function or having fungal and viral infections in the airways.

You should rinse your mouth out with water after each dosage to minimise the risk of fungal infection in your mouth and throat.

You must contact your doctor if your asthma gets worse. This may mean that the dosage needs to be changed or that you need other treatment.

In an acute asthma attack you must use your fast-acting asthma medicine.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including obtained without a prescription. These include CYP3A4 inhibitors such as ketoconazole and itraconazole; to treat fungal infection.

Some medicines may increase the effects of PULVISIONIDE and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor or pharmacist will advise you.

How to use PULVISIONIDE

- How much to use

Adult:

200 mcg twice daily in the morning and evening. The daily doses may increase up to 1600 mcg in more severe cases.

Children 6 years and above:

200-800 mcg daily in 2 to 4 divided doses. The highest recommended dose in children is 400 mcg twice daily.

- When to use it

Use as directed by your doctor or pharmacist.

Your doctor prescribes the correct dose for you. The number of doses varies according to the severity of your asthma.

PULVISIONIDE is entirely driven by your own inhalation. The medicine follows the inhaled air down to the airways. Therefore, it is important to breathe in deeply and forcefully when you take your dose, see "How to use PULVISIONIDE inhaler properly".

Note that the amount of medicine is very small and it can be very hard to notice. You might not be able to taste or detect the medicine in any way. However, if you follow the instructions for use, you can be sure that you have inhaled the dose.

How to use your PULVISIONIDE inhaler properly

1. Remove the protection cap from inhaler (Figure 1)



(Figure 1)

2. Hold the base of the inhaler firmly.
3. Open the inhaler by turning the mouthpiece in the direction of the arrows. (Figure 2)

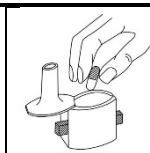


(Figure 2)

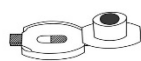
4. Take a capsule and place it in the capsule chamber of the inhaler. (Figure 3 and Figure 4).

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(Figure 3)



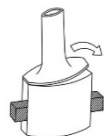
(Figure 4)



(Figure 8)

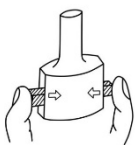
5. Check whether the capsule is completely inside the capsule chamber. If not, put the capsule in correctly.

6. Close the inhaler by turning the mouthpiece back to the closed position. (Figure 5)



(Figure 5)

7. Hold the inhaler upright (with the mouthpiece upwards). Hold the push buttons between thumb and index finger. Use both fingers at the same time to press these buttons once. (Figure 6). The capsule is now evenly punctured.



(Figure 6)

8. Deeply breathe out (not through the inhaler). (Figure 7) After that, hold the inhaler horizontally.



(Figure 7)

9. Tilt your head back slightly. Insert the mouthpiece of the inhaler completely into your mouth, behind your teeth and on your tongue. Close your lips tight round the mouthpiece. (Figure 8).

10. Breathe in rapidly but steadily, as deeply and forcefully as you can. The inhaler makes a rattling noise if it is operating properly. This is because the capsule spins in the chamber as the powder disperses.

11. Remove the inhaler from your mouth. Hold your breath for about 5-10 seconds so that your lungs can take up the medication. Breathe out gently.

12. Open the inhaler and check whether the capsule is empty, if not repeat from step 8-11.

13. Open the inhaler and remove the empty capsule. Put the protection cap back on the inhaler.

Instruction to clean:

- You should clean inhaler of PULVISONIDE once a week.

1. Open the inhaler by turning the mouthpiece as far as possible in the direction of the arrows.

2. Rinse the mouthpiece with running water.

3. Before using the inhaler again, it should be completely dry.

- How long to use it

Continue taking PULVISONIDE for as long as your doctor recommends.

You must use PULVISONIDE regularly, i.e., each day, even if you have no symptoms.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you have forgotten to take one dose, take the next dose as usual.

- If you use too much (overdose)

If you have taken a larger dose than your doctor has been prescribed on one occasion, you will probably not suffer from any side effects. If you think that you are suffering from side effects, contact your doctor or hospital for information about the risk and advice.

It is important that you take the dose stated on the label of the packaging or as your doctor has told you. Do not increase or decrease the dose without contacting your doctor

While you are using it

- Things you must do

- Use PULVISONIDE as directed by your doctor.
- PULVISONIDE should only be used with inhaler and inhaled through your mouth (oral inhalation).
- Rinse mouth after each use.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give PULVISONIDE to anyone else, even if they have the same symptoms or condition as you.
- Do not intake or swallow PULVISONIDE capsule.

- Things to be careful of

- PULVISONIDE should always be stored in blister and only removed immediately before use. The capsules should not be stored in the inhaler.
- You are advised to rinse your mouth with water after each dosing to reduce the risk of oral fungal infection.
- Pregnancy and Lactation**
Experience from usage during pregnancy does not show any increased risk of malformations. However, you must talk to your doctor before using PULVISONIDE during pregnancy because the severity of the asthma may

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change and the treatment may need to be adjusted.

Budesonide is excreted in breast milk. However, no effects on the nursing child are anticipated with therapeutic doses of PULVISONIDE. PULVISONIDE can be used during breast-feeding.

• *Driving and using machines*

PULVISONIDE does not affect your ability to drive a car or use machines.

Side effects

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

Common:

Mild irritation of the throat, coughing, hoarseness, fungal infection in the mouth cavity and throat.

Pneumonia (infection of the lung) in COPD patients (common side effect)

• Tell your doctor if you have any of the following while taking PULVISONIDE, they could be symptoms of a lung infection:

- Fever or chills;
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties

Rare:

Hives and other skin rashes, angioedema (swelling of the face, lips, tongue and/or throat, occasionally combined with difficulty breathing or swallowing), bronchospasm (contraction of the airway muscles), bruising.

The following have been reported (occur in an unknown number of users):

Sleep disturbances, depression, anxiety, feeling of being very upset and/or irritable. These side effects are more likely to occur in children.

Inhaled corticosteroids can affect the normal production of steroid hormones in your body, particularly if you use

high doses for a long time. The effects include:

- Changes in bone mineral (thinning of the bones)
- Cataract (clouding of the lens in the eye)
- Glaucoma (increased pressure in the eye)
- Decreased growth rate in children and adolescents
- An effect on the adrenal gland (a small gland next to the kidney)
- These effects are much less likely to happen with inhaled corticosteroids than with cortisone tablets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PULVISONIDE

- Storage

Do not store above 30°C.

Keep medicines out of reach of children.

Replace the mouthpiece cap firmly.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White powder filled in brown clear - colorless capsule no.3 with/without dry powder inhaler, PREZHALER.

- Ingredients

- Active ingredient
Budesonide 200 mcg
- Inactive ingredients
Lactose monohydrate

- MAL number:

MAL23026016AZ

Manufacturer

T.O CHEMICALS (1979) Ltd.
53 Moo 4, Bueng-Kham-Phroi,
Lam-luk-ka, Pathumthani
12150 THAILAND

Product Registration Holder

IMEKS Pharma Sdn Bhd
No. 5 & 9, Jalan Udang Harimau 2,
Medan Niaga Kepong,
51200 Kuala Lumpur.

Date of revision

30/06/2023

Serial Number

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