CONSUMER MEDICINE INFORMATION

AFT Pharmaceuticals

Budenocort 200 and 400

Budesonide 200 mcg/actuation and 400 mcg/actuation, powder for inhalation in metered inhaler

What is in this leaflet

Read this leaflet carefully before you start using this medicine.
This leaflet answers some common questions about Budenocort. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the possible risks of you using Budenocort against the benefits they expect it will have for you.

If you have any concerns about using Budenocort, talk with your doctor or pharmacist.
Keep this leaflet. You may need to read it again.

What the medicine is used for

Budenocort is a dry powder inhaler that contains budesonide. Budenocort 200 gives a dose of 200 mcg/actuation, Budenocort 400 gives a dose of 400 mcg/actuation.
Budenoside belongs to a family of medicines called corticosteroids.

When you breathe in Budenocort, it goes into your lungs and reduces or prevents the inflammation in them that causes asthma.

Asthma is a disease where the lining of the lungs becomes swollen or inflamed (red and swollen), making it difficult to breathe. Budenocort acts directly on your air passages to reduce inflammation. This helps to improve your condition and to prevent asthma attacks from occurring. Budenocort is a "preventer" and needs to be taken regularly.

Your doctor may have prescribed Budenocort for another reason. Ask you doctor if you have any questions about why Budenocort has been prescribed for you.
Budenocort is only available with a doctor's prescription. It has been prescribed for you. You should not give this medicine to them even if their symptoms are the same as yours.

Budenocort is not recommended for use in children under 6 years of age.

Before you take this medicine

When you must not take it
Do not use Budenocort if you are allergic to budesonide or lactose.
Do not use Budenocort to treat an acute asthma attack.
Do not use Budenocort after the expiry date printed on the pack. It may not work as well.
Do not use if the packaging is torn or shows signs of tampering.

Before you start to take the medicine
Tell your doctor or pharmacist:
- About any allergies you may have
- If you are using any other medicine including any you may have bought without a prescription from a pharmacy, supermarket or health shop
- If you are pregnant or thinking of becoming pregnant
- If you are breast-feeding or planning to start breast-feeding
- If you have a cold, chest infection or any breathing problems
- If you currently have any infection as Budenocort may hide some of the signs of infection making you mistakenly think that you are better or it is not serious.
- If you have or have ever had tuberculosis (TB)

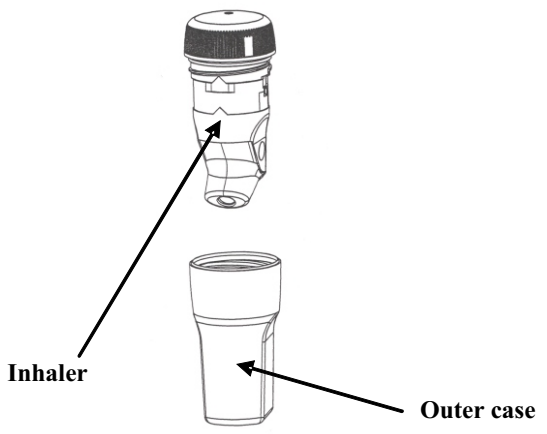
How to use the Medicine

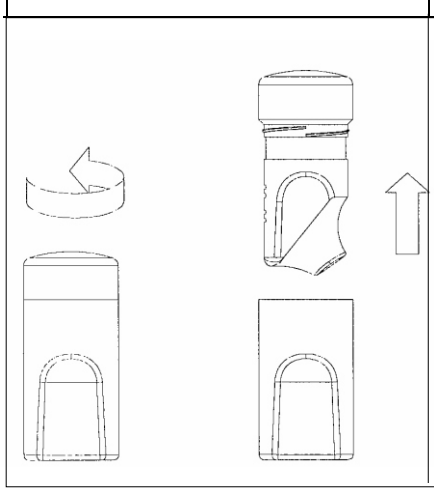
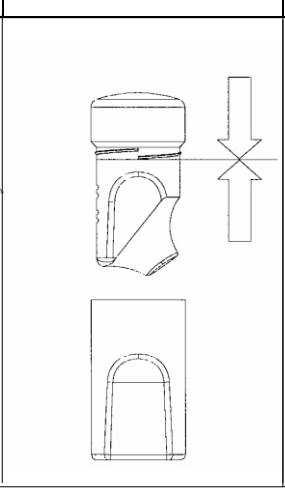
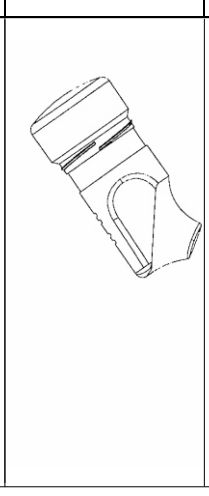
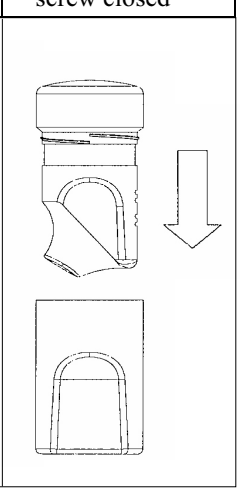
Budenocort is presented in a device called the Miat-Haler®, an inspiratory flow-driven device which when the patient activates the device and inhales through the mouthpiece, the budesonide will follow the inspired air into the airways.

The inhaler is packed in an aluminium blister in the outer carton. The blister should not be opened or the inhaler removed from it until it is necessary to use the inhaler. The inhaler may rattle when shaken. This is not a cause for concern it is part of the mechanism.

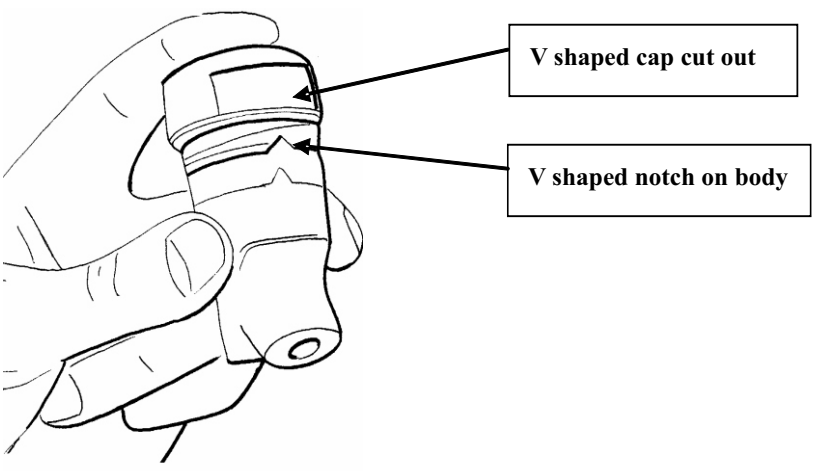
The inhaler is easy to use when the instructions are followed.
It is important to:
- breathe in as deeply and hard as possible through the mouthpiece to ensure that an optimal dose is delivered to the lungs. never to breathe out through the mouthpiece
- rinse their mouth out with water after inhaling the prescribed dose to minimise the risk of oropharyngeal thrush
- replace the inhaler in the outer case after use. This will make it ready for the next dose.

The Miat-Haler consists of two pieces as shown below. It is light grey except for the cap which is dark brown.



1. Unscrew inhaler and remove from case keeping in an upright position	2. Depress brown cap	3. Inhale	4. Replace inhaler in case and screw closed
			

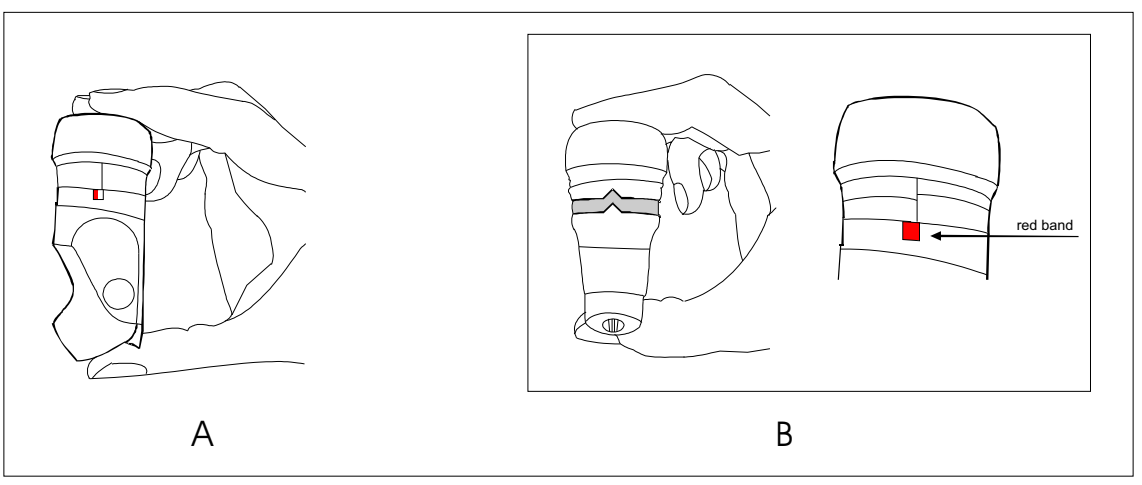
1. If the device is not held upright when unscrewing it from the case it will make a clicking sound to remind you. Unscrew the brown cap (anticlockwise) and remove from the case. Unscrewing the brown cap actuates the device.
2. The brown cap must be pressed to prepare the dose of medicine for use. The V shaped notch on the body must be aligned with the V shape on the cap or the device will not operate. The inhaler should be held correctly thus:



3. Breathe out gently (not into the inhaler), then place the inhaler in the mouth. Breathe in as deeply and hard as possible. Remove inhaler from mouth and hold breath for 10 seconds or as long as is comfortable.
4. Clean the outside of the mouthpiece with a dry tissue after use. Never use water or any other liquid. Replace inhaler in the outer case and screw closed (clockwise). If it is not held upright it will make a clicking noise.
5. If 2 inhalations are required repeat steps 1-4.
6. After taking wash mouth out with water and/or clean teeth. This will reduce the risk of oropharyngeal thrush.

You may not notice any taste in your mouth when using Budenocort but you will have received the correct dose.
You cannot accidentally take a double dose of Budenocort even if you remove the inhaler from the case and do not use it before replacing it.
Children may need assistance from an adult when using their inhaler.

As your inhaler becomes nearly empty, a red band will begin to appear in the window. When it is empty, after the labelled number of actuations have been used, the red band will fill the window. The brown top will not depress as it will lock to stop you using an empty inhaler. You should see your doctor for a replacement prescription when the red band first appears.



How much to take
Always take Budenocort exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

Usual doses

Adults (including the elderly and children over 12 years of age): 200 - 800 mcg once daily up to a maximum of 800 mcg twice daily.

Children 6 to 12 years of age: 200 - 400 mcg once daily up to a maximum of 400 mcg twice daily.

The dose may need to be increased during periods of severe asthma or during periods of stress. Your doctor will advise you on this.

Use Budenocort at the same time every day.

If you forget to take it
If it is almost time for your next dose, skip the dose you missed and take your next dose when you meant to.
Otherwise, use it as soon as you remember and then go back to using as you would normally.
Do not take a double dose to make up for a dose that you missed.

While taking the medicine

You should contact your doctor immediately if:
- Your breathing starts getting worse
- You wake up a lot during the night with asthma or wheeziness
- You start getting chest tightness when you wake in the morning
- Your morning chest tightness starts lasting longer than usual.

Although your breathing may improve immediately you start taking Budenocort, it is usually several weeks before you notice the full benefits. Do not stop taking Budenocort when your asthma improves, your doctor will tell you when to stop taking Budenocort. You must take Budenocort regularly for it to work properly.

Do not use Budenocort to treat a sudden asthma attack. You should use your relief inhaler.

If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.

Tell any doctors, dentists and pharmacists who are treating you that you are using Budenocort for your asthma.
If you are about to be started on any new medicine tell you doctor or pharmacist that you are using Budenocort.
If you are going to have surgery using a general anaethsthetic tell your doctor or dentist that you are using Budenocort.
If you become pregnant while using Budenocort tell your doctor.

Side effects
Like all medicines, Budenocort can have side effects. Talk to your doctor or pharmacist if you have any questions.

You should contact your doctor immediately if you notice any of the following:
- Acute wheezing
- Skin rash
- Swelling of the face particularly around the mouth
- Bruising
- Feeling nervous or anxious
- Mood changes

Common side effects which are usually mild and don't last long are:
- Sore, creamy-yellow, raised patches in the mouth (thrush). Talk to your doctor or pharmacist as soon as possible about treatment. Rinsing your mouth with water and cleaning your teeth after each dose of Budenocort can reduce the possibility of thrush occurring.
- Hoarse voice
- Sore mouth, throat or tongue
- Headache
- Tiredness
- Feeling light-headed
- Thirst
- Unpleasant taste in mouth
- Nausea
- Diarrhoea
- Weight gain

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Overdose
If you think you or anyone else has taken too much Budenocort, telephone your doctor, or the Poisons Information Centre on 0800 POISON (0800 764 766) or go to the Accident and Emergency Department at your nearest hospital.

Storage
Store below 25 ºC. Do not refrigerate or freeze.
Keep the container tightly closed to protect from moisture. In the bottom of the inhaler case there is a desiccant pill. Do not remove this from the case as it will help protect the medicine from moisture. Do not eat the desiccant pill.

Other ingredients
Budenocort also contains lactose.

If you want to know more
Ask your doctor or pharmacist.

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