BUNASE

Budesonide Pressurized Inhalation BP 200mcg/actuation

What is in this leaflet?

1. What Bunase is used for
2. How Bunase works
3. Before you use Bunase
4. How to use Bunase
5. While you are using Bunase
6. Side effects
7. Storage and Disposal of Bunase
8. Product description
9. Manufacturer
10. Product Registration Holder
11. Serial Number

What Bunase is used for

Bunase is a medicine called "preventer". It treats the inflammation and it is used to prevent symptoms of asthma. It belongs to a group of medicines called corticosteroids (also known as steroids). It works by reducing andpreventing swelling and inflammation in your lungs.
Bunase is a pressurized inhalation suspension and containsa medicine called budesonide. Bunase contains 200 micrograms budesonide per actuation. Budesonide will not stopan asthma attack that has already started. Therefore, youalways need to have a fast acting bronchodilating "reliever" (abeta2-agonist) with you.
Your doctor has prescribed this medicine to treat asthma.
However, it should not be used to relieve an acute attack of asthma.

How Bunase works

The activity of Budesonidse is dueto the parent drug, Bunase. In glucocorticoid receptor affinity studies, the 22R form was two times as active as the 22S epimer. In vitro studies indicated that the two forms of Bunase do not interconvert. The precise mechanism of corticosteroid actions on inflammation in asthmais not known. Inflammation is an important component in the pathogenesis of asthma.
Corticosteroids have been shownto have a wide range of inhibitory activities against multiple cell types (eg, mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (eg, histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic and non-allergic-mediated inflammation. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in asthma.

Before you use Bunase

- *When you must not use it*

If you are allergic (hypersensitive) to budesonide, or any of the other ingredients of Bunase.

- You have tuberculosis (TB)

Do not use Bunase if any of the above apply to you. If youare not sure, talk to your doctor, nurse or pharmacist before using Bunase.

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

Take special care with Bunase

Before you start to use it, talk to your doctor or pharmacist before using Budesonide inhaler if:

- You have a known infection of the airways (such as bacterial, viral orfungal infection
- You have had tyberculosis(TB) in the past.
- You have a cold or chest infection.
- You have liver problems.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Bunase.

- *Before you start to use it*

Talk to your doctor or pharmacist before using Bidesonide inhaler if:

- You have a lung infection
- You have a cold or chest infection or any problems with your breathing.
- You have or have ever had tuberculosis (TB).
- You have liver problems.

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

- *Taking other medicines:*

Tell your doctor or pharmacist if you are taking, have recently takenor might take any other medicines.This includes medicines that you buy without a prescription and herbal medicines. This is because Bunase inhaler can affect the way some medicines work and some medicines can have an effect on Bunase inhaler and your doctor may wish to monitor you carefully.
In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other steroid medicines that you inhale, such as aerosol inhaler, powder inhaler or nebulising solutions.
- Steroid medicines that you take by mouth (such as prednisolone).
- Medicine to treat fungal infections (such as itraconazole andketoconazole).
- HIV medicines (such as ritonavir or corbistat-containing products).

If you have to see another doctor orgoing into hospital, make sure you take with you all of your inhalers and other medicines you have beenprescribed or have bought without a prescription. If possible, these should be in original packaging.

Pregnancy & Breast-feeding

- If you are pregnant or planning to become pregnant, talk to your doctor before using Bunase, do not use it unless your doctor tells you to.
- If you get pregnant or think you might be pregnant while using inhaler, do not stop using it but talk to your doctor immediately.
- If you are breast feeding,talk to your doctor beforeusing Bunase.

Driving and using machines:

Bunase is not likely to affect you being able to drive or use any tools or machines.

Information you may have to carry while you are using Bunase:

If you are using a high dose of Bunase, your doctor may ask you to carry a steroid warning card. This explains to others about your medication.

BUNASE

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How to use Bunase

- *How much to be use*:
  - Always take this medicine exactly as your doctor, nurse or pharmacist has told you. Check with one of them if you are not sure.
  - Bunase is used by breathing the medicine contained in the inhaler inthrough your mouth.
  - Your doctor or nurse will show you how to use Bunase. The instructions are given in the sections below called 'How to use your inhaler'. Carefully read them before using inhaler for the first time.
  - It is important to use the inhaler every day, even if you have no asthma symptoms at the time.
  - Please check the label put on the inhaler by your pharmacist for further instructions on how many puffs (actuations) to take and how often to take your medicine.
  - If you are unsure how to use your spacer device properly please speak to your doctor, asthma nurse or pharmacist.

If you have been taking steroids tablets for your asthma, your doctor may reduce the number of tablets that you take, once you start to use Bunase. If you have been taking oral steroid tablets for a long time, your doctor may want you to have blood tests from time to time. When reducing oral steroid tablets, you may feel generally unwell even though your symptoms may be improving. You might experience symptoms such as a stuffy or runny nose, weakness or joint or muscle pain and rash (eczema). If any of these symptoms bother you, or if symptoms such as headache, tiredness, nausea (feeling sick) or vomitting (being sick) occur, please contact your doctor immediately.

You may need to take other medication if you develop allergic or arthritis symptoms. You should speak to your doctor if you are concerned as to whether you should continue to use Bunase.

Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Your doctor may ask you to carry a steroid warning card to explain to others about your medication.

Important information about your asthma symptoms

If you feel you are getting breathless or wheezy while using Bunase, you should continue to use it but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is gettingworse or you often wake up at night with asthma.
- Your chest starts to feel tight in the morning or your chest tightness lastslonger than usual.
- You are not getting reliefffrom your 'relief inhaler'or you need more puffs than usual to treat your symptoms.
- If you feel your treatment is becoming less effective,or not lasting as long as it usually does.
- You have an acute asthma attack; if you have an acute asthma attack you should use your 'reliever inhaler' straightaway and contact your doctor immediately.

These symptoms and signs could mean that your asthma is not well controlled and you may need different or additional treatment immediately.

Use Bunase every day. This helps to prevent asthma symptoms your doctor or asthma nurse will help you to manage your asthma. Your doctor asthma nurse or pharmacist will advise you on how, when and how often you should use your inhaler. They will also tell you howmany puff (actuations) to take at any one time. This dose that your doctor has prescribed for you will depend on how severe your asthma is, your doctor or asthma nurse will adjust the dose of this medicine to lowest dose that controls your asthma. Do not change the dose yourself or suddenly stop using Bunase without talking to your doctor or asthma nurse first.

The number of puffs that you need to take will depend on which strength of Bunase your doctor has prescribed.

Budesonide Pressurized Inhalation BP 200mcg

Initially, at the beginning of inhaled corticosteroid therapy, for therapy during periods of severe asthma or when scaling down or withdrawing oral corticosteroids the dosage should be:

Children aged 2-7 years:
200-400 micrograms per day divided into 2 administrations.

Children aged 7 years and older:
200-800 micrograms per day divided into 2 administrations.

Adults:
200-1600 micrograms per day divided into 2 administrations.

For maintenance treatment administration twice daily, morning and evening, is usually sufficient. The maintenance dose should be the lowest possible. Following a single dose an effect may be expected after a few hours. The full therapeuticeffect is only achieved after a few weeks of treatment.

Bunase is not to be used by children less than 2 years of age. Use your separate 'reliever inhaler' to treat asthma symptoms when they happen. Always keep your 'reliever inhaler' with you to use when you need it. Do not use Bunase to treat asthma symptoms use your 'reliever inhaler'.

Preparing your Bunase

Before using your new Bunase (Budesonide) Pressurized Inhalation for the first time, or if you have not used your inhaler for more than 7 days or if ithas been dropped, you need to prime it for use as follows:

BUNASE

Budesonide Pressurized Inhalation BP 200mcg/actuation

- Remove the dust cap from the plastic adapter. Check that the mouth piece is clean and not blocked.
- Shake the inhaler so that the contents of the aerosol canister areproperly mixed.
- Press the canister twice to release two puffs into the air.
- Your inhaler is now ready for use.

How to use your inhaler

Bunase is used by breathing the medicine contained in theinhaler in through your mouth. It is important that you donot rush using your inhaler. At first, you may need to practise using the inhaler in front of the mirror. Any mist coming from thetop of the inhaler or from the mouthpiecemay mean that you have not inhaled the medicines properly. Young children may need help from their parent or carers to use the inhaler.
Your doctor, nurse or pharmacist will regularly check how you use your inhaler.

Every time you need to take an inhalation, follow the instruction below:

1. Remove the dust cap from the plastic adapter. Shake the inhaler so that thecontent of the aerosol canister are properly mixed before each use.
2. Hold your Bunase upright. Breathe out as far as possible.
3. Place the mouth piece between your lips. Do not chew or bite on the mouthpiece. Start to breathe in slowly and deeply through your mouth. Keep breathing in and press the canister firmly to release a puff from inhaler. You may need to use both hands to release a puff from your inhaler. Keep breathing in for a short while afterpressing the canister.
4. Hold your breathe for 10 seconds, or for as long as is comfortable. Hold your inhaler away from your mouth. Then breathe outslowly, if you are to take a second puff, wait at least half a minute. Then shake the inhaler and repeat steps 2,3, and
5. After use, replace the dust cap on the plastic adapter. Store your inhaler so that it is sitting upright on its brown plastic base.
6. Rinse your mouth with water and spit it out.

Cleaning your inhaler

Clean the inhaler once a week. Remove the dust cap and the aerosol canister. Clean the plastic actuator and dust cap with a dry cloth or tissue. Then relapse the aerosol canister and dust cap. Do not put the inhaler into water.

If you use more Bunase

If too much Bunase is used on a single occasion, no harmful effects should occur. If too much Bunase is used over a long period (weeks or months). It is possible that side effects may arise.If you use more Bunase, contact your doctor, nurse or pharmacist for advise as soon as possible.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

The time period for taking Bunase depends on your doctor's instruction. Hence, follow your doctor's instruction.

- *If you forgot to takeBunase*

If you forgot to take a dose, take it as soon as you remember. Howeverif it is nearly time for the next dose do not take the missed dose.

Do not take a double dose (2 dosses at the same time) to make up for a forgotten dose.
Do not stop using this medicinewithout talking to your doctor.

- *If you use too much(Overdose)*

It is important that you take your dose as stated on the pharmacists label or as advised by your doctor. You must not increase or decrease your dose without seeking medical advice. It you use more Bunase actuation than you should, contact your doctor or pharmacist advice.

While you are using Bunase

- *Things you must do*

Take Bunase by mouth, with or without food.

-*Things you must not do*

Bunase is not likely to affect you being able to drive or use any tools or machines.

-*Things to be careful of:*

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 using this medicine. Do not use Bunase unless your doctor tells you to.
If you get pregnant while using Bunase, do not stop using Bunase but talk to your doctor immediately.

Side effects

Like all medicines, Bunase pMDI Inhalation can cause side effects, although not everybody gets them.

Important side effect to look out for:

- Swelling of your face, particularly around your mouth (with possible swelling of the lips, tongue,eyes and ears) rash, itching,contact dermatitis (a skin problem), hives and bronchospasm (tightening of the muscle in the airways which causes wheezing). If any of this reactions occur, this may mean that you are having an allergic reactions to Budesonide Pressurized Inhalation. You must stop using Budesonide Pressurized Inhalation straightway and seek medical device immediately. This rarely happens affecting less thanin 1000 people.
- Sudden acute wheezing or shortness of breathes immediately after usingyour inhaler. If either of these symptoms occurs,stop using BudesonidePressurized Inhalation straightaway and use your reliever inhaler. Contact your doctor immediately as you may need to have your treatment changed. This happen very rarely affecting less than 1 in 10000 people.

Other possible side effects: Common (affect less than 1 in 10people) Rare (affect less than 1 in 1000 people)

- Feeling restless or nervousness
- Depression
- Changes in behavior
- Bruising of the skin

The following side may also occur particularly if a high dose is taken for a long time or if steroids tablets have also been prescribed or have been taken previously:

- Changes in bone mineraldensity (thinning of bones)
- Cataract (Clouding of thelens in the eye)
- Glaucoma (increased pressure in the eye)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly. By reporting side effects, you can help provide more information on the safety of this medicine.

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

Storage and disposal of Bunase

- Keep out of reach and sight of children.
- Do not store above 30°C.
- Do not remove Budesonide Pressurized Inhalation from the outer carton until you are ready to use it. Store the carton in the position indicated.
- Always replace the dust cap after using your inhaler.
- Always store Budesonide Pressurized Inhalation so that it is sitting upright on its brown plastic base.
- Do not use BudesonudePressurized Inhalation after the expiry date printed on the label andcarton. The expiry date refers to thelast day of the month.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

Warning: The canister contains a pressurized liquid. Do not expose to temperature higher than 50°C. Do not pierce the canister. The canister should not be broken, punctured or burnt, even when it seems to be empty.

Product description

What it looks like and contents of the pack

Each carton contains Pressurized metered inhaler containing suspension aerosol fitted in plain aluminium canister fitted with suitable metered valve provided with brown coloured cap and white body colour body and a patient information leaflet.

Ingredients:

- Active ingredient: Budesonide BP

- Inactive ingredients: 1,1,1,2 Tetrafluoroethane (Propellant HFA 134A)

MAL no.: MAL24046013ACZ

Manufacturer:
Oxalis Lab
Village Theda, P.O.Lodhimajra, Tehsil Baddi, Dist.Solan (H.P)-174 101, India

Product Registration Holder: Macleods Pharmaceuticals Sdn. Bhd.
A2-27-1 Soho Suites KLCC, Jalan Perak, 50450 Kuala Lumpur, Malaysia.

Date of revision:
22/08/2024

Serial Number
NPRA(R2)21/09

PACKAGING RESEARCH & DEVELOPMENT

OXALIS LABS

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

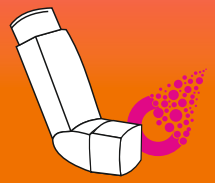
Patient Information Leaflet

Before using the Bunase inhaler read this leaflet carefully and follow the instructions.

200 Metered Actuations

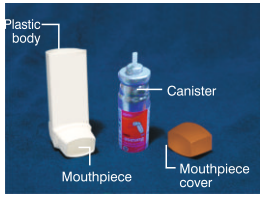
Bunase

(Budesonide) Pressurized Inhalation BP 200mcg/actuation



MACLEODS

PARTS OF THE INHALER



HOW TO USE YOUR INHALER CORRECTLY

Testing Your Inhaler

Before using your inhaler for the first time, or if it has not been used for a week or more, "test fire" it, i.e. release one puff into the air.



USING YOUR INHALER

1 Remove the mouthpiece cover, and check that the mouthpiece is clean. Shake the inhaler well. Hold the inhaler upright as shown, with your thumb on the base. Place either one or two fingers on top of the canister.



2 Breathe out gently, through your mouth.



3 Place the mouthpiece of the inhaler in your mouth between your teeth and close your lips around it (Do not bite it.)



Start breathing in slowly through your mouth. As you breathe in, press down the canister to release one dose while continuing to breathe in steadily and deeply.



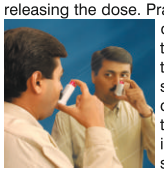
4 Remove the inhaler from your mouth and hold your breath for 10 seconds, or for as long as it is comfortable. Breathe out slowly.



5 If another dose is required wait for at least one minute. Repeat steps 2 to 4. After use, replace the mouthpiece cover.

Important

Do not rush steps 3 to 4. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practice in front of mirror for the first few times. If you see "mist" coming from the top of the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.





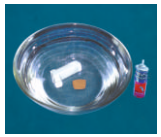
6 After inhalation is complete, rinse your mouth with water without swallowing it.

Cleansing

It is essential to keep the plastic mouthpiece clean, to ensure proper functioning of the inhaler. Clean your inhaler at least once a week, as follows:



1 Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.

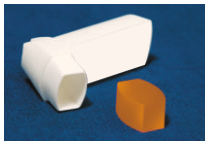


2 Immerse the plastic body and the mouth-piece cover in warm water. Do not put the metal canister in the water.

3 Next, rinse the plastic body and mouthpiece cover under running tap water.



4 Shake well to remove excess water. Leave to dry. Avoid the use of heat to dry the parts.



5 When the plastic body is dry, replace the canister and the mouthpiece cover correctly.

Warning

1. If the recommended dose does not provide the desired effect, consult your doctor. It is dangerous to exceed the recommended dose.
2. The metal canister is pressurized. Do not puncture or burn it even when empty.
3. Keep away from eyes.
4. Keep away from children.

CFC FREE