NEW ZEALAND CONSUMER MEDICINE INFORMATION

ALANASE 100
Beclometasone dipropionate Nasal Spray
100 microgram (µg) per spray

What is in this leaflet

Please read this leaflet carefully before you start using ALANASE 100.

This leaflet answers some common questions about ALANASE 100. 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 has weighed the risks of using ALANASE 100 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What ALANASE 100 is used for

ALANASE 100 is used to prevent and treat seasonal and perennial allergic rhinitis (including hay fever) and vasomotor rhinitis. It works by reducing the swelling and irritation in the lining of the nose. It relieves the symptoms of blocked nose, runny nose, itchy nose and sneezing.

ALANASE 100 may also be used to delay the recurrence of nasal polyps in patients who have undergone nasal polypectomy. It can suppress the increase in size of the polyps that do recur.

ALANASE 100 contains 100 micrograms (µg) of beclometasone dipropionate per spray. It belongs to a group of medicines known as corticosteroids, frequently referred to as ‘steroids’. They are not ‘anabolic steroids’ that are sometimes misused by athletes.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

• nasal or sinus infection
• recent injury or surgery to your nose
• ulceration in your nose
• bleed easily or get frequent nose bleeds.

Tell your doctor or pharmacist if you ever have had to stop taking another medicine for your hay fever.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using ALANASE 100.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are using ALANASE 100.

Before you use ALANASE 100

When you must not use it

Do not use ALANASE 100 if you have an allergy to:

• any medicine containing beclometasone
• any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.
Some medicines may interfere with ALANASE 100. These include:

- medicines used to treat HIV such as ritonavir and cobicistat

These medicines may be affected by ALANASE 100 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use ALANASE 100

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Instructions for use

1. Shake the bottle well before use. Remove the dust cap from the nasal applicator.

2. Hold the nasal spray as shown. Prime the pump by firmly pressing downwards on the white collar. Repeat until a fine spray is produced. The nasal spray is now ready for use. It will not require repriming unless infrequently used or disassembled.

3. Gently blow your nose to clear the nostrils. Tilt your head forward slightly, close one nostril and carefully insert the nasal applicator into the other nostril.

4. Holding the bottle upright, press firmly downwards once on the white collar. Breathe gently inwards through the nostril.

5. Then breathe out through your mouth.

6. Repeat the procedure in the other nostril.

7. Replace the dust cap.

Cleaning your applicator

Your nasal applicator should be cleaned at least once a week, or more often if it gets blocked. To clean, remove the dust cap, press gently upwards on the white collar and the nasal applicator will come free. Wash the applicator and dust cap under lukewarm water. Dry and replace.

If the nasal applicator becomes blocked, remove the dust cap, unscrew the pump mechanism from the bottle and soak it in warm water for a few minutes. Rinse under lukewarm water, dry and reassemble on the bottle. Do not attempt to unblock the applicator with a pin or other sharp object.

How much to use

It is important that you use ALANASE 100 exactly as advised by your doctor or pharmacist. Do not use more than recommended; using more or less may make your symptoms worse.

The usual dosage for adults and children over 6 years of age is one spray into each nostril twice daily (morning and night).

Your doctor may tell you to use a different dosage to this. If so, follow their instructions.

You should not use more than 400 micrograms (µg) (equivalent to 2 sprays per nostril) in a day.

How to use it

You must use your spray for your nose only. If you find it difficult to use your spray, tell your doctor or pharmacist.

ALANASE 100 should be shaken before use.

When to use it

Use your medicine at about the same times each day. Using it at the same times each day will have the best effect. It will also help you remember when to use it.

If you know you are going to be allergic to, for example, pollen at a particular time of the year, it is helpful to start using your spray just before your symptoms appear to prevent them from starting.

How long to use it

It usually takes a few days for this medicine to help your nasal symptoms.

Continuous long-term treatment of children is not recommended.

Do not use ALANASE 100 for more than 6 months unless instructed by your doctor.

If you forget to use it

Skip the dose you missed and use your next dose when you are meant to.

Do not use a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.
While you are using ALANASE 100

Things you must do
If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using ALANASE 100.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you become pregnant while using ALANASE 100, tell your doctor immediately.

Things you must not do
Do not use ALANASE 100 to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of
Be careful driving or operating machinery until you know how ALANASE 100 affects you. This medicine may cause blurred vision in some people. If you have any of this symptom, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

In case of overdose

If you use too much (overdose)
Immediately telephone your doctor, pharmacist or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have used too much ALANASE. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

Side effects
Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ALANASE 100. This medicine helps most people with rhinitis (runny or blocked nose, sneezing, facial pressure or pain), but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:
- sneezing
- affected taste or smell

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:
- dry and/or irritated nose
- dry and/or irritated throat
- nosebleed
- redness of skin
- damage or sores on the inside of your nose

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:
- red eyes
- blurred vision
- headache
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body which may cause difficulties in swallowing or breathing

- rash, itching or hives on the skin
- chest tightness

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these side effects (for example, high eye pressure) can only be found when your doctor does tests from time to time to check your progress.

Studies have shown that the active ingredient in ALANASE 100 (beclometasone dipropionate) when taken through the nose for long periods may affect how children grow. In rare cases, some children may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's height.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

After using ALANASE 100

Storage
Keep ALANASE 100 in a cool place away from direct sunlight where the temperature stays below 25°C. Do not put your ALANASE 100 in the refrigerator.

Keep the bottle in an upright position.

Do not store ALANASE 100 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
Once you have opened your spray, you should not use this particular bottle for more than three months. Write down the date that you opened the bottle on the label or the box.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ALANASE 100 comes in an amber glass bottle fitted with a pump, and nasal applicator. Each bottle provides approximately 200 sprays, when used as recommended.

Ingredients

Active ingredient:
ALANASE 100 contains 100 micrograms (µg) of beclometasone dipropionate per spray as the active ingredient.

Inactive ingredients:
ALANASE 100 also contains:
- polysorbate
- dispersible cellulose
- glucose (anhydrous)
- purified water
- benzalkonium chloride
- phenethyl alcohol.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

ALANASE 100 is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Information

6 August 2019
(Based on datasheet dated 6 August 2019).