

BUTACORT 50

50 micrograms (µg) per spray
Budesonide Nasal Spray



What is in this leaflet

This leaflet answers some common questions about Butacort 50.

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 you using Butacort 50 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 Butacort 50 is used for

Butacort 50 contains the active ingredient budesonide. 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.

Butacort 50 is normally used to prevent and treat seasonal allergic rhinitis (hayfever), which is an inflammation or swelling of the nose lining. This is often, but not always, due to an allergy to something in the air.

Butacort 50 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.

Butacort 50 may also be used for the relief of symptoms associated with nasal polyps.

Your doctor or pharmacist, however, may recommend Butacort 50 for another purpose.

Butacort 50 is only available at a pharmacy.

There is no evidence that Butacort 50 is addictive.

Before you use Butacort 50

When you must not use it

Do not use Butacort 50 if you have an allergy to:

- any medicine containing budesonide
- 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 if you have a severe infection, especially thrush, in your nose.

Do not use this medicine if you bleed easily or have recurring nose bleeds.

Do not use Butacort 50 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.

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

Before you start to use it

Tell your doctor or pharmacist if you are allergic to:

- any other corticosteroid medicines
- 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, sinus or chest infection
- have severe nasal congestion or obstruction
- tuberculosis
- have recently had an injury or surgery to your nose
- have open sores in your nose.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start using Butacort 50.

Taking other medicines

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

Some medicines and Butacort 50 may interfere with each other. These include:

- other corticosteroid medicines, such as tablets, asthma inhalers, nasal sprays, or eye/nose drops.
- some medicines used to treat fungal infections such as ketoconazole, itraconazole, fluconazole
- cimetidine, a medicine used to treat reflux and stomach ulcers

These medicines may be affected by Butacort 50 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

This list of medicines is not complete. Your doctor and pharmacist have more information on medicines to be careful with while using Butacort 50 with other medicines.

How to use Butacort 50

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 carton, ask your 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 or twice on the white collar to deliver the number of sprays required. 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

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 Butacort 50 exactly as directed 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 12 years is initially one or two sprays into each nostril twice a day (morning and night), then after 2 to 3 days, one spray into each nostril twice a day.

Your doctor may tell you to use different doses to these. If so, follow their instructions.

Do not use Butacort 50 for children under 12 years of age without first consulting with a doctor.

You must use Butacort 50 for your nose only. If you find it difficult to use your spray, talk to your doctor or pharmacist.

Butacort 50 should be shaken before use.

How long to use it

It usually takes 2 to 3 days before you notice any improvement in your symptoms.

If you suffer from hayfever, you should start your treatment just before the hayfever season to prevent symptoms from starting.

If hayfever symptoms do not improve within 7 days of treatment, see your doctor.

Do not use for more than 6 months unless instructed by your doctor or pharmacist.

When to use it

Use your medicine at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

It does not matter if you use Butacort 50 before or after food.

If you forget to use it

If you forget a dose, just take the next dose at the normal time. Do not take a double dose. 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 use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

Immediately telephone your doctor, pharmacist or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have used too much Butacort 50. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Butacort 50

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Butacort 50.

Tell any other doctors, dentists, and pharmacists who treat you that you are using Butacort 50.

If you become pregnant while taking Butacort 50, tell your doctor immediately.

Things you must not do

Do not use Butacort 50 to treat any other complaints unless your doctor tells you to.

Do not give Butacort 50 to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Butacort 50.

This medicine helps most people with hayfever 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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:

- nose irritation
- nose bleeds
- increased amount of mucous, nasal crust
- sneezing after spraying
- headache
- itching or sore throat
- dry mouth
- earache
- cough
- nausea, loss of appetite
- itchy skin
- tiredness
- tremor

The above list includes the more common side effects of your medicine. They are usually mild.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- sign or symptoms of a severe nasal infection such as fever, pain or swelling, or discoloured nasal discharges, acute eye pain or visual disturbance

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

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.

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

After using Butacort 50

Storage

Keep Butacort 50 in a cool dry place where the temperature stays below 25°C.

Do not store Butacort 50 in the refrigerator.

Do not store Butacort 50 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.

Keep the bottle in an upright position.

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 taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

Butacort 50 comes in an amber glass bottle fitted with a pump, and nasal applicator. Each bottle provides approximately 200 sprays, when used as recommended.

Ingredients

Butacort 50 contains 50 micrograms (μg) of budesonide as the active ingredient per spray.

It also contains:

- disodium edetate
- dispersible cellulose
- glucose (anhydrous)
- hydrochloric acid
- polysorbate
- purified water
- potassium sorbate (preservative)

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

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 168 169

Date of Information

13 March 2012 (Based on datasheet dated 26 August 2011)