

Foracort Inhaler 160/4.5

Budesonide 160 mcg/actuation and Formoterol Fumarate Dihydrate 4.5 mcg/actuation

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What is FORACORT used for

FORACORT is an inhaler that is used to treat asthma in adults and adolescents 12 years of age and older. It is also used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 years and older.

Asthma

FORACORT is prescribed as a daily maintenance dose and a separate 'reliever inhaler' is needed for symptom relief.

- They use FORACORT every day. This helps to prevent asthma symptoms from happening.
- They use their 'reliever inhaler' when they get asthma symptoms, to make it easier to breathe again.

Chronic Obstructive Pulmonary Disease (COPD)

FORACORT can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

How FORACORT works

FORACORT is an inhaler. It contains two different medicines: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called 'corticosteroids'. It works by reducing and preventing swelling and inflammation in your lungs.

- Formoterol fumarate dihydrate belongs to a group of medicines called 'long-acting β_2 adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Before you use FORACORT

-When you must not use it

FORACORT should not be used in cases of known hypersensitivity to the active ingredients budesonide and formoterol or to any of the excipients.

-Before you start to use it

Before you use FORACORT, tell your doctor or pharmacist if:

- You are diabetic.
- You have a lung infection.
- You have high blood pressure, or you have ever had a heart problem (including an uneven heartbeat, a very fast pulse, narrowing of the arteries or heart failure).
- You have problems with your thyroid or adrenal glands.
- You have low levels of potassium in your blood.
- You have severe liver problems.

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

-Taking other medications

Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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

In particular, tell your doctor or pharmacist if you are using any of the following medicines:

- Beta-blocker medicines (such as atenolol or propranolol for high blood pressure), including eyedrops (such as timolol for glaucoma).

- Medicines for a fast or uneven heartbeat (such as quinidine).
- Medicines like digoxin, often used to treat heart failure.
- Diuretics, also known as 'water tablets' (such as furosemide). These are used to treat high blood pressure.
- Steroid medicines that you take by mouth (such as prednisolone).
- Xanthine medicines (such as theophylline or aminophylline). These are often used to treat asthma.
- Other bronchodilators (such as salbutamol).
- Tricyclic anti-depressants (such as amitriptyline) and the anti-depressant nefazodone.
- Phenothiazine medicines (such as chlorpromazine and prochlorperazine).
- Medicines called 'HIV-protease inhibitors' (such as ritonavir) to treat HIV infection.
- Medicines to treat infections (such as ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin and telithromycin).
- Medicines for Parkinson's disease (such as levodopa).
- Medicines for thyroid problems (such as levothyroxine).

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

Also tell your doctor or pharmacist if you are going to have a general anaesthetic for an operation or for dental work.

How to use FORACORT

-How much to use & When to use it

- Always use FORACORT exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- It is important to use FORACORT every day, even if you have no asthma or COPD symptoms at the time.

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- If you are using FORACORT for asthma, your doctor will want to regularly check your symptoms.

If you have been taking steroid tablets for your asthma or COPD, your doctor may reduce the number of tablets that you take, once you start to use FORACORT. 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 chest symptoms may be improving. You might experience symptoms such as a stuffy nose 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 vomiting (being sick) occur, please contact your doctor immediately. You may need to take other medication if you develop allergic or arthritic symptoms.

You should speak to your doctor if you are concerned as to whether you should continue to use FORACORT.

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).

Important information about your asthma or COPD symptoms

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

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night with asthma.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your asthma or COPD is not properly controlled and you may need

different or additional treatment immediately.

Usually, the following dosage guidelines apply.

Dosage for asthma

Adults and adolescents over 12 years of age:

2 puffs one to two times daily. Your doctor may prescribe you a maximum of up to 4 puffs twice daily.

Dosage for Chronic Obstructive Pulmonary Disease (COPD)

Adults (18 years and older):

2 inhalations twice daily.

-How long to use it

- Always use FORACORT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- It is important to use FORACORT every day, even if you have no asthma or COPD symptoms at the time.
- If you are using FORACORT for asthma, your doctor will want to regularly check your symptoms.

-If you forget to use it

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-If you use too much (overdose)

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not exceed your prescribed dose without seeking medical advice.

The most common symptoms that may occur after if you use more FORACORT than you should are

trembling, headache or a rapid heartbeat.

While you are using it

-Things you must do

Use FORACORT as directed by your doctor.

-Things you must not do

Do not stop using FORACORT unless advised by your doctor.

-Things to be careful of

Pregnancy and breastfeeding:

- If you are pregnant, or planning to get pregnant, talk to your doctor before using FORACORT - do not use FORACORT unless your doctor tells you to.
- If you get pregnant while using FORACORT, do not stop using FORACORT but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using FORACORT.

Driving and using machines:

FORACORT has no or negligible effect on your ability to drive or to use tools or machines.

Side effects

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

If either of the following happens to you, stop using FORACORT and talk to your doctor immediately:

- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) or hives together with difficulties to breathe (angioedema) and sudden feeling of faintness. This may mean that you are having an allergic reaction. This happens rarely, affecting less than 1 in 1,000 people.
- Sudden acute wheezing or shortness of breath immediately after using your inhaler. If either

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of these symptoms occur, stop using your FORACORT straightaway and use your 'reliever' inhaler. Contact your doctor immediately as you may need to have your treatment changed. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Palpitations (awareness of your heart beating), trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use FORACORT.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your FORACORT.
- Mild sore throat, coughing and a hoarse voice.
- Headache.
- Pneumonia (infection of the lung) in COPD patients.

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

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

Uncommon (may affect up to 1 in 100 people)

- Feeling restless, nervous or agitated.
- Disturbed sleep.
- Feeling dizzy.
- Nausea (feeling sick).
- Fast heartbeat.
- Bruising of the skin.
- Muscle cramps.
- Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Rash, itching.
- Bronchospasm (tightening of the muscles in the airways which

causes wheezing). If the wheezing comes on suddenly after using FORACORT stop using FORACORT and talk to your doctor immediately

- Low levels of potassium in your blood
- Uneven heartbeat.

Very rare (may affect up to 1 in 10,000 people)

- Depression.
- Changes in behaviour, especially in children.
- Chest pain or tightness in the chest (angina pectoris).
- An increase in the amount of sugar (glucose) in your blood.
- Taste changes, such as an unpleasant taste in the mouth.
- Changes in your blood pressure.

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 density (thinning of the bones).
- Cataract (clouding of the lens in the eye).
- Glaucoma (increased pressure in the eye).
- A slowing of the rate of growth of 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 corticosteroid tablets.

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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via local reporting system. 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 reaction directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of FORACORT

-Storage

- FORACORT should be stored below 30 °C and it should be kept out of the reach of children. The drug may only be used up to the date indicated on the package under "EXP".
- After removing the foil, the metered dose inhaler may only be used within 3 months. Store the metered dose inhaler with the mouthpiece facing down and the counter facing up.
- The container of FORACORT metered dose inhaler is pressurized.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like

Foracort Inhaler 160/4.5 is a white to off-white coloured suspension filled in an aluminium aerosol canister fitted into a white polypropylene actuator with a dose counter (120 doses) and a brown polypropylene dust cap. Each inhaler is wrapped in a foil laminate pouch containing a drying agent.

-Ingredients

- Active ingredient(s)
1 actuation of FORACORT metered dose inhaler 160/4.5 contains 160 µg budesonide and 4.5 µg formoterol fumarate dihydrate.

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- Inactive ingredient(s)
Heptafluoro propane,
Povidone and Macrogol
1000.

-MAL number

MALXXXXXXXXAZ

Manufacturer

Cipla Limited - Unit II, Plot No. 9 and 10, Indore Special Economic Zone, Phase II, Pithampur, District Dhar, Pincode: 454775, Madhya Pradesh, India

Product Registration Holder

Cipla Malaysia Sdn. Bhd.
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Date of revision

-21/05/2026

Serial Number

NPRA(R2)25/214

Instructions for Use

Application

Before your first application, note the last date you can use the metered dose inhaler. This is 3 months from the moment the protective foil was opened.

Preparation of the metered dose inhaler

Take the metered dose inhaler out of the protective foil before using it for the first time and throw the foil away. Your metered dose inhaler is ready to use, please do not disassemble it (figure 1).

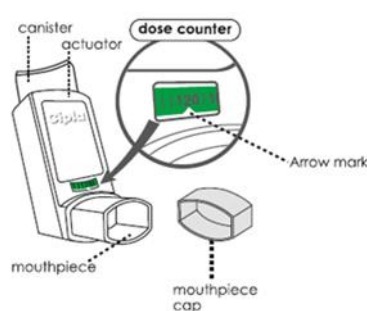


Figure 1

Before using the metered dose inhaler for the first time, if you have not used it for more than a week, or if it has been dropped, gently shake it and release two puffs into the air (see figure 2).

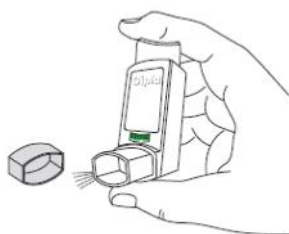


Figure 2

Method of administration

1. Shake the metered dose inhaler gently.
2. Remove the protective mouthpiece cap by gently squeezing and pulling it out.
3. Hold the metered dose inhaler upright between your thumb and index finger (figure 2). Exhale as strongly as possible holding the mouthpiece in your mouth between your teeth and wrapping your lips around it (figure 3).



Figure 3

4. Begin breathing slowly and deeply through your mouth while pressing firmly on the container (figure 2,3).
5. Continue to inhale and hold your breath for approximately 10 seconds or as long as it is comfortable. Then take the metered dose inhaler out of your mouth and stop pressing down on the container.
6. Shake the container again and repeat points 3 to 5.
7. After application, put the protective cap back on.
8. Rinse your mouth with water to prevent any drug residue.

Routine care for mouthpiece

The mouthpiece must be cleaned regularly, at least once a week. Proceed as follows:

1. Remove the protective cap.
2. Wipe the inside and outside of the mouthpiece with a clean, dry cloth.
3. Put the protective cap back on.
4. Do not try to disassemble the metered dose inhaler.

Never put the metered dose inhaler in water!

How do you know when your metered inhaler device no longer have doses available?

Your inhaler device has a counter that shows how many doses are still available. The counter, indicated by a small arrow, starts at 120. Each time you inhale a dose or spray it into the air, the arrow will move towards "0". If the arrow points to "0", you must use a new metered dose inhaler, even if the metered dose inhaler does not yet appear to be empty. You would no longer inhale the correct dose.