Package leaflet: Information for the user

Foracort 160 micrograms /4.5 micrograms per actuation pressurised inhalation, suspension
budesonide/formoterol fumarate dihydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <Invented name> is and what it is used for
2. What you need to know before you use <Invented name>
3. How to use <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

1. What <Invented name> is and what it is used for

<Invented name> is an inhaler that is used to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) in adults aged 18 and older. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking. <Invented name> 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 $beta_2$ adrenoceptor agonists' or 'bronchodilators'. It works by relaxing the muscles in your airways. This helps you to breathe more easily.

Do not use this medicine as a "reliever" inhaler.

2. What you need to know before you use <Invented name>

Do not use <Invented name>:
- if you are allergic to budesonide, formoterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using <Invented name> 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 heart beat, 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.

Children and adolescents
<Invented name> is not recommended for children and adolescents under 18 years.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 heart beat (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 COPD or 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 leva-dopa).
- Medicines for thyroid problems (such as levo-thyroxine).

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

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

Pregnancy, breast-feeding and fertility
- If you are pregnant, or planning to get pregnant, talk to your doctor before using <Invented name> - do not use <Invented name> unless your doctor tells you to.
- If you get pregnant while using <Invented name>, do not stop using <Invented name> but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using this medicine.

Driving and using machines
<Invented name> has no or negligible effect on your ability to drive or to use tools or machines.

3. How to use <Invented name>

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

The usual dose is 2 inhalations twice a day. <Invented name> is not recommended for children or adolescents under 18 years of age.

If you have been taking steroid tablets for your COPD, your doctor may reduce the number of tablets that you take, once you start to use <Invented name>. 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 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 <Invented name>.

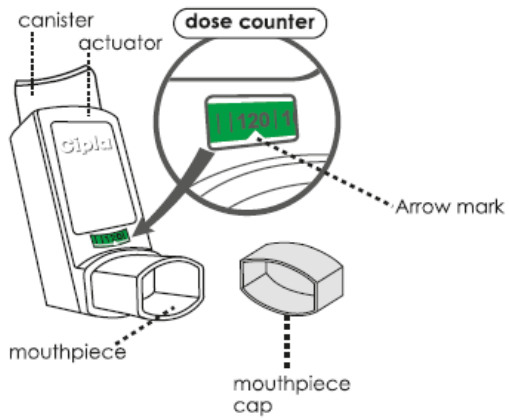
Your doctor may consider adding steroid tablets to your usual treatment during periods of stress (for example, when you have a chest infection or before an operation).

Important information about your COPD symptoms
If you feel you are getting breathless or wheezy while using <Invented name>, you should continue to use this medicine 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 feeling breathless.
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.
- These signs could mean that your COPD is not being properly controlled and you may need different or additional treatment immediately.

Your doctor may also prescribe other bronchodilator drugs, for example anticholinergics (such as tiotropium or ipratropium bromide) for your COPD disease.

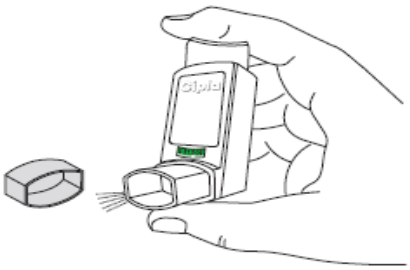
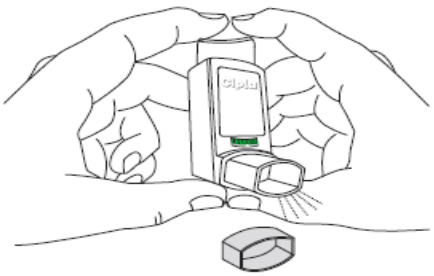
Information about your <Invented name>
- Before starting to use your <Invented name>, remove it from the foil wrapper. Throw away the wrapper as well as the drying agent which is inside the wrapper. If the drying agent has leaked out of its packet, do not use the inhaler.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening the wrapper) on the inhaler label to remind you when to stop using the inhaler.
- The parts of your inhaler are shown in the picture. The inhaler will already be assembled when you first receive it. Do not take it apart. If the canister becomes loose, put it back in the inhaler and keep using the inhaler.



Preparing your <Invented name>
You need to prepare your inhaler for use in the following situations:
- If you are using your new <Invented name> for the first time.
- If you have not used it for more than 7 days.
- If it has been dropped.

To prepare your inhaler for use, follow the instructions below:

1. Shake the inhaler well for at least 5 seconds to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover.
3. Hold the inhaler upright. Then press the counter (on top of the inhaler) to release a puff into the air. You can use one or both hands, as shown in the pictures.

4. Release your finger(s) from the canister.
5. Wait for 10 seconds, shake well and then repeat steps 3 and 4.
6. Your inhaler is now ready for use.

How to take an inhalation
Each time you need to take an inhalation, follow the instructions below:

1. Shake the inhaler well for at least 5 seconds to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover. Check that the mouthpiece is not blocked.
3. Hold your inhaler upright (using one or both hands). Breathe out gently.
4. Place the mouthpiece gently between your teeth. Close your lips.
5. Start to breathe in slowly and deeply through your mouth. Press the canister (on the top of the inhaler) firmly to release a puff. Keep breathing in for a short while after pressing the canister. Breathing in at the same time as pressing the canister ensures that the medicine reaches your lungs.

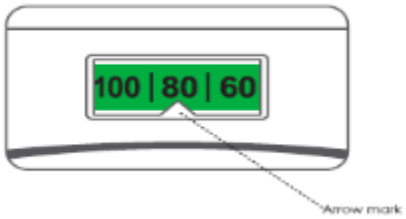


6. Hold your breath for 10 seconds, or for as long as it is comfortable.
7. Before you breathe out, release your finger from the canister and remove the inhaler from your mouth. Keep the inhaler upright.
8. Then breathe out slowly. To take another inhalation, shake the inhaler well for at least 5 seconds and repeat steps 3 to 7.
9. Replace the mouthpiece cover.
10. Rinse your mouth with water after your daily morning and evening doses and spit it out.

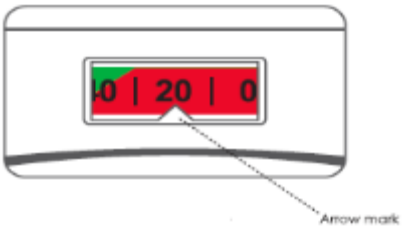
Using a spacer device
Your doctor, nurse or pharmacist may suggest that you use a spacer device (e.g. ***AeroChamber Plus Flow Vu*** or ***AeroChamber Plus***). Follow the instructions in the leaflet that is packed with the spacer device.

Cleaning your <Invented name>
- Wipe the inside and outside of the mouthpiece at least once a week with a dry tissue.
- Do not use water or liquids and do not remove the canister from the inhaler.

How will I know when to replace my <Invented name>?
- The counter on the front of your inhaler tells you how many puffs (actuations) are left in your <Invented name>. It starts with 120 puffs when it is full.



- Each time you take an inhalation, or release a puff into the air, the arrow counts down towards zero (‘0’).
- When the arrow enters the red area, this means that there are about 20 puffs left.



- You must stop using your <Invented name>, and should get a new inhaler, when the arrow reaches ‘0’. Your inhaler may not feel empty and it may seem as though it still works. However, you will not get the right amount of medicine if you keep using it.

If you use more <Invented name> than you should
If you use more <Invented name> than you should, contact your doctor or pharmacist for advice. The following effects may happen: trembling, headache or a rapid heartbeat.

If you forget to use <Invented name>
- 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 stop using <Invented name>
Before you stop using <Invented name>, you should talk to your doctor or your pharmacist. If you stop using <Invented name> the signs and symptoms of COPD may worsen.

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

4. Possible side effects

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

If either of the following happens to you, stop using <Invented name> straightaway and talk to your doctor immediately:
- Swelling of your face, particularly around your mouth (tongue and/or throat and/or difficulty to swallow) rash or hives together with difficulties to breathe (angioedema) and/or 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 of these symptoms occurs, stop using your <Invented name> 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 <Invented name>.
- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your <Invented name>.
- 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 <Invented name>, 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 heart beat.
- 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 <Invented name> stop using this medicine and talk to your doctor immediately.
- Low levels of potassium in your blood.
- Uneven heart beat.

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.

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 via the national reporting

system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label, carton and foil wrapper after EXP. The expiry date refers to the last day of that month.
- Before first opening:
  Store in the original package in order to protect from light. Do not refrigerate or freeze.
- After first opening:
  Do not store above 25°C. Store in the original package in order to protect from light. Do not refrigerate or freeze.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening wrapper) on the inhaler label to remind you when to stop using the inhaler.
- Always replace the mouthpiece cover firmly and snap into position after using your inhaler.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

6. Contents of the pack and other information

What <Invented name> contains

- The active substances are budesonide and formoterol fumarate dihydrate. Each puff (actuation) contains 160 micrograms of budesonide and 4.5 micrograms of formoterol fumarate dihydrate.
- The other ingredients are Apafkurane (HFA-227), Povidone and Macrogol.
- This medicine contains fluorinated greenhouse gases. Each inhaler contains 11.1 g of apaflurane (HFC-227ea) corresponding to 0.035 tonne CO_2 equivalent (global warming potential GWP= 3,220).

What <Invented name> looks like and contents of the pack

<Invented name> is an inhaler containing your medicine. The pressurised canister, with attached dose indicator, contains a white suspension for inhalation. The canister is fitted into a white polypropylene actuator integrated with dose counter with brown plastic dust cap. Each inhaler contains 120 puffs (actuations) after it has been prepared for use. Each inhaler is individually wrapped in a four ply laminated foil pouch containing a drying agent.

<Invented name> is available in packs of one inhaler.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last revised in {MM/YYYY}.

7 May 2025