

Cipla Budesonide + Formoterol 200/6

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Cipla Budesonide + Formoterol 200/6?

Cipla Budesonide + Formoterol 200/6 contains two active ingredients in one inhaler: budesonide and formoterol fumarate dihydrate. Cipla Budesonide + Formoterol 200/6 is used for treatment of asthma in adults and adolescents (12 years and over) or Chronic Obstructive Pulmonary Disease (COPD) in adults (18 years and over).

For more information, see Section [1. Why am I using Cipla Budesonide + Formoterol 200/6?](#) in the full CMI.

2. What should I know before I use Cipla Budesonide + Formoterol 200/6?

Do not use if you have ever had an allergic reaction to any medicine containing budesonide or formoterol, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Cipla Budesonide + Formoterol 200/6?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cipla Budesonide + Formoterol 200/6 and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Cipla Budesonide + Formoterol 200/6?

- Cipla Budesonide + Formoterol 200/6 should be inhaled into your lungs through the mouth.
- Follow all directions given to you by your doctor or pharmacist.

More instructions can be found in Section [4. How do I use Cipla Budesonide + Formoterol 200/6?](#) in the full CMI.

5. What should I know while using Cipla Budesonide + Formoterol 200/6?

Things you should do	<ul style="list-style-type: none">• If you have an Asthma Action Plan agreed with your doctor, follow it closely at all times.• Have your reliever medicine available at all times. As advised by your doctor, this may be your Cipla Budesonide + Formoterol 200/6 or another reliever medicine.• Rinse your mouth out with water after taking your daily morning and/or evening dose of Cipla Budesonide + Formoterol 200/6 and spit this out.• Remind any doctor, dentist or pharmacist you visit that you are using Cipla Budesonide + Formoterol 200/6.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor
Driving or using machines	<ul style="list-style-type: none">• Cipla Budesonide + Formoterol 200/6 may cause dizziness, light-headedness, tiredness or drowsiness in some people when they first start using it.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Cipla Budesonide + Formoterol 200/6 in a cool dry place where the temperature stays below 25°C, with the cover firmly in place.• Dispose your Cipla Budesonide + Formoterol 200/6 3 months after removal from the foil pouch.

For more information, see Section [5. What should I know while using Cipla Budesonide + Formoterol 200/6?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include sore, yellowish, raised patches in the mouth (thrush), hoarse voice, unpleasant taste in your mouth, pounding heart, headache, trembling or muscle cramps. However, some side effects may need medical attention. These include severe allergic reactions such as difficulty breathing, swelling of the face, lips or tongue, severe rash or pneumonia (lung infection), signs include fever or chills, increased phlegm or a change in colour, increased cough or difficulties breathing. Serious side effects are rare.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cipla Budesonide + Formoterol 200/6

Active ingredient(s): *budesonide / formoterol fumarate dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cipla Budesonide + Formoterol 200/6. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cipla Budesonide + Formoterol 200/6.**

Where to find information in this leaflet:

- [1. Why am I using Cipla Budesonide + Formoterol 200/6?](#)
- [2. What should I know before I use Cipla Budesonide + Formoterol 200/6?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Cipla Budesonide + Formoterol 200/6?](#)
- [5. What should I know while using Cipla Budesonide + Formoterol 200/6?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Cipla Budesonide + Formoterol 200/6?

Cipla Budesonide + Formoterol 200/6 is a pressurised metered dose inhaler (pMDI) or puffer. It contains two active ingredients in one inhaler: budesonide and formoterol fumarate dihydrate.

- Budesonide belongs to a group of medicines called corticosteroids. Budesonide acts directly on your airways to reduce inflammation.
- Formoterol belongs to a group of medicines called beta-2-agonists. Formoterol opens up the airways to help you breathe more easily.

The medicine inside Cipla Budesonide + Formoterol 200/6 is inhaled into the lungs for the treatment of asthma in adults and adolescents (12 years and over) or Chronic Obstructive Pulmonary Disease (COPD) in adults (18 years and over).

Asthma

Asthma is a disease where the airways of the lungs become narrow and inflamed (swollen), making it difficult to breathe. This may for example be due to exercise, or exposure to allergens (e.g. an allergy to house dust mites, smoke or air pollution), or other things that irritate your lungs.

The budesonide in Cipla Budesonide + Formoterol 200/6 helps to improve your condition and to prevent asthma attacks from occurring. The formoterol in Cipla Budesonide + Formoterol 200/6 helps you breathe more easily.

Some people can take Cipla Budesonide + Formoterol 200/6 when they need it – they use Cipla Budesonide + Formoterol 200/6 as an anti-inflammatory reliever to treat their symptoms when their asthma gets worse and to help prevent asthma attacks, or to help prevent symptoms from happening (eg before exercise or exposure to other triggers such as allergens).

Some people need to take Cipla Budesonide + Formoterol 200/6 every day – they use their Cipla Budesonide + Formoterol 200/6 as a daily maintenance preventer to help maintain control of their asthma symptoms and help prevent asthma attacks.

Chronic Obstructive Pulmonary Disease (COPD)

COPD (which includes chronic bronchitis and emphysema) is a long-term lung disease. There is often permanent narrowing and persistent inflammation of the airways. Symptoms may include difficulty in breathing (breathlessness or wheezing), coughing and increased sputum (phlegm).

Cipla Budesonide + Formoterol 200/6 when used as prescribed will help to control your COPD symptoms (ie breathing difficulties).

2. What should I know before I use Cipla Budesonide + Formoterol 200/6?

Warnings

Do not use Cipla Budesonide + Formoterol 200/6 if:

- you are allergic to any medicine containing budesonide or formoterol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any allergies to any other medicines or foods.
- have, or have had, any of the following medical conditions, as it may not be safe for you to take Cipla Budesonide + Formoterol 200/6:
 - thyroid problems
 - diabetes
 - heart problems
 - liver problems
 - tuberculosis (TB)
 - low levels of potassium in the blood.
- currently have an infection. If you take Cipla Budesonide + Formoterol 200/6 while you have an infection, the medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.
- have any other medical conditions.

- have any questions about how you should be using your Cipla Budesonide + Formoterol 200/6.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the possible risks and benefits of using Cipla Budesonide + Formoterol 200/6 during pregnancy and while breastfeeding.

Children

Do not give Cipla Budesonide + Formoterol 200/6 to a child under 12 years, unless directed to by the child's doctor.

Cipla Budesonide + Formoterol 200/6 is not recommended for use in children under 12 years.

Asthma Action Plan

If you have asthma, ask your doctor or pharmacist if you have any questions about your Asthma Action Plan.

Your healthcare professional should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take as a reliever when you have symptoms or sudden attacks of asthma, medicines you can take to prevent symptoms from occurring (eg prior to exercise or allergen exposure) and if you need to take daily maintenance medicines to help control your asthma. It will also provide advice on when to seek urgent medical attention such as when your asthma suddenly worsens or worsens over a period of time.

It is important that you discuss with your doctor both your exposure to triggers and how often your exercise, as these could impact how your doctor prescribes your Cipla Budesonide + Formoterol 200/6.

3. What if I am taking other medicines?

Some medicines may interfere with Cipla Budesonide + Formoterol 200/6 and affect how it works. These include:

- medicines used to treat heart problems or high blood pressure such as beta-blockers, diuretics and antiarrhythmics (disopyramide, procainamide and quinidine)
- medicines used to treat glaucoma such as beta-blockers

- medicines used to treat depression or other mood/mental disorders such as tricyclic antidepressants, monoamine oxidase inhibitors and phenothiazines
- medicines used to treat hayfever, coughs, colds and runny nose such as antihistamines
- medicines used to treat fungal infections (eg ketoconazole)
- xanthine derivatives (eg theophylline) which are a class of medicines used to treat asthma and COPD
- medicines used to treat Addison's disease (when there is inadequate production of a natural steroid hormone by the adrenal gland) or another condition where there is too much salt loss in the urine (eg fludrocortisone)

These medicines may be affected by Cipla Budesonide + Formoterol 200/6 or may affect how well it works. You may need different amounts of your medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cipla Budesonide + Formoterol 200/6.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Cipla Budesonide + Formoterol 200/6.

4. How do I use Cipla Budesonide + Formoterol 200/6?

How to use your Cipla Budesonide + Formoterol 200/6

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Please read instruction for use which tells you the correct way to use it carefully.

If you are not sure how to use the Cipla Budesonide + Formoterol 200/6, ask your doctor or pharmacist to show you how.

How much to take

Asthma (Adults and children 12 years and over)

Your healthcare professional should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take as a reliever when you have symptoms or sudden attacks of asthma, medicines you take prevent symptoms from occurring (eg prior to exercise or allergen exposure) and if you need to take daily maintenance medicines to help control your asthma.

It is important that you discuss with your doctor both your exposure to triggers and how often you exercise, as these could impact how your doctor prescribes your Cipla Budesonide + Formoterol 200/6.

Your doctor may have prescribed Cipla Budesonide + Formoterol 200/6 for you to use as:

- a. an anti-inflammatory reliever medicine only,
- b. both an anti-inflammatory reliever and daily maintenance preventer medicine or,
- c. as a daily maintenance preventer only, where another medicine is used as a reliever.

If your asthma has been under control for some time, your doctor may tell you to take less inhalations of Cipla Budesonide + Formoterol 200/6, prescribe you a lower strength of Cipla Budesonide + Formoterol 200/6 or recommend that you use Cipla Budesonide + Formoterol 200/6 in a different way.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor as your asthma may be getting worse.

Ask your doctor if you have any questions about how you should be using your Cipla Budesonide + Formoterol 200/6.

Anti-inflammatory reliever only (Cipla Budesonide + Formoterol 200/6)

For patients aged 12 years and over, Cipla Budesonide + Formoterol 200/6 can be used to treat asthma symptoms when they happen and to help stop asthma symptoms from happening (eg just before exercise or before you get exposed to other triggers).

If you get asthma symptoms, take 1 inhalation and wait a few minutes. If you do not feel better, take 1 more inhalation.

Your doctor will tell you how many inhalations to take before exercising or exposure to other triggers to help stop symptoms from happening.

Do not use more than 6 inhalations on a single occasion or more than 12 inhalations in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.

Have your Cipla Budesonide + Formoterol 200/6 reliever with you at all times.

Anti-inflammatory reliever plus maintenance therapy (Cipla Budesonide + Formoterol 200/6)

For patients aged 12 years and over, Cipla Budesonide + Formoterol 200/6 can be used to treat asthma symptoms when they happen. Cipla Budesonide + Formoterol 200/6 can also be used to help stop asthma symptoms from

happening (eg just before exercise or before you get exposed to other triggers).

If you get asthma symptoms, take 1 inhalation of Cipla Budesonide + Formoterol 200/6 and wait a few minutes. If you do not feel better, take 1 more inhalation.

Your doctor will tell you how many inhalations of Symbicort Cipla Budesonide + Formoterol 200/6 to take before exercising or exposure to other triggers to help stop symptoms from happening.

Have your Cipla Budesonide + Formoterol 200/6 reliever with you at all times.

You also need to take your Cipla Budesonide + Formoterol 200/6 daily as your maintenance preventer. The usual maintenance dose is 2 inhalations per day (given either as 1 inhalation in the morning and evening or as 2 inhalations in either the morning or evening). Your doctor may prescribe a maintenance dose of Cipla Budesonide + Formoterol 200/6, 2 inhalations twice a day.

Do not use more than 6 inhalations on a single occasion or more than 12 inhalations of Cipla Budesonide + Formoterol 200/6 (as needed and daily dose) in any day. If your symptoms continue to worsen over 3 days, despite using additional inhalations, tell your doctor.

Daily fixed dose maintenance therapy (Cipla Budesonide + Formoterol 200/6)

For patients aged 12 years and over, Cipla Budesonide + Formoterol 200/6 can be used as a daily fixed-dose maintenance preventer.

The usual dose of Cipla Budesonide + Formoterol 200/6 is 2 inhalations twice a day. Do not take more than 4 inhalations a day.

Cipla Budesonide + Formoterol 200/6 can also be given as a higher dose in patients aged 18 years and over. The usual dose is 4 inhalations twice a day. Do not take more than 8 inhalations per day.

Have your separate reliever with you at all times.

COPD (Adults)

The usual dose (also maximum recommended dose) is 2 inhalations of Cipla Budesonide + Formoterol 200/6 twice a day.

Your doctor should tell you the best way to manage your symptoms and any flare ups. This may include additional medicines (such as reliever medicines) to use when you have sudden attacks of breathlessness.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor.

If your COPD gets worse, your doctor may give you some additional medicines (such as oral corticosteroids or antibiotics).

How long to use your Cipla Budesonide + Formoterol 200/6

If your doctor has told you to take Cipla Budesonide + Formoterol 200/6 daily, it is important that you use it every day even if you feel well.

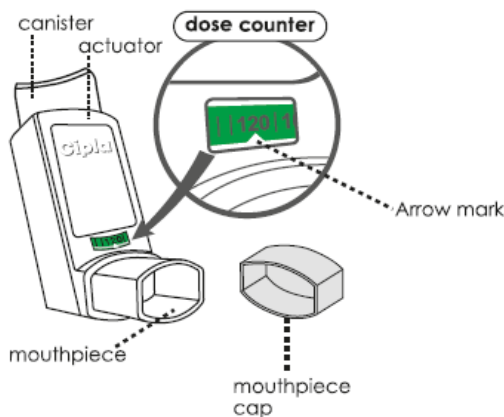
Cipla Budesonide + Formoterol 200/6 helps control your asthma or COPD but does not cure it.

Keep using it for as long as your doctor tells you to. Do not stop using it unless your doctor tells you to.

Instructions for use

Information about your Cipla Budesonide + Formoterol 200/6

- Before starting to use your Cipla Budesonide + Formoterol 200/6, 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 Cipla Budesonide + Formoterol 200/6

You need to prepare your inhaler for use in the following situations:

- If you are using your new Cipla Budesonide + Formoterol 200/6 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

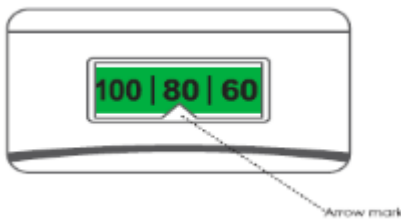
Your doctor, nurse or pharmacist may suggest that you use a spacer device (e.g. **AeroChamber Plus Flow Vu** or **AeroChamber Plus**). Follow the instructions in the leaflet that is packed with the spacer device.

Cleaning your Cipla Budesonide + Formoterol 200/6

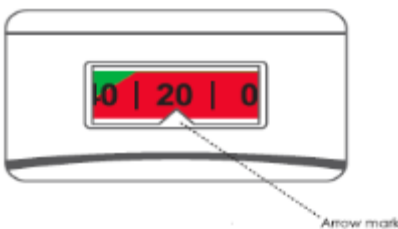
- Wipe the inside and outside of the mouthpiece at least once a week with a dry tissue.
- Do not use water or liquids and do not remove the canister from the inhaler.

How will I know when to replace my Cipla Budesonide + Formoterol 200/6?

- The counter on the front of your inhaler tells you how many puffs (actuations) are left in your Cipla Budesonide + Formoterol 200/6. 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.



- When the arrow reaches '0', you must stop using your new Cipla Budesonide + Formoterol 200/6. 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 forget to use Cipla Budesonide + Formoterol 200/6

If you miss a dose of Cipla Budesonide + Formoterol 200/6, take your dose as soon as you remember.

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 using Cipla Budesonide + Formoterol 200/6 as a reliever medicine, consult your doctor on the correct use of the product.

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 Cipla Budesonide + Formoterol 200/6

If you think that you have used too much Cipla Budesonide + Formoterol 200/6, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you use too much Cipla Budesonide + Formoterol 200/6, you may feel sick or vomit, have a fast or irregular heartbeat, a headache, tremble, feel shaky, agitated, anxious, tense, restless, excited or be unable to sleep.

5. What should I know while using Cipla Budesonide + Formoterol 200/6?

Things you should do

- **If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.**
- **Keep using Cipla Budesonide + Formoterol 200/6 for as long as your doctor tells you to, even if you are feeling well.**
- **See your doctor regularly to make sure that your asthma or COPD is not getting worse.**
- **Have your reliever medicine available at all times.** As advised by your doctor, this may be your Cipla Budesonide + Formoterol 200/6 or another reliever medicine.
- **If you become pregnant while using Cipla Budesonide + Formoterol 200/6, tell your doctor.**
- **Rinse your mouth out with water after taking your daily morning and/or evening dose of Cipla Budesonide + Formoterol 200/6 and spit this out.** If you don't rinse your mouth, you are more likely to develop thrush in your mouth. You do not have to rinse mouth if you have to take occasional doses of Cipla Budesonide + Formoterol 200/6 for relief of asthma symptoms (ie as an anti-inflammatory reliever).
- **Tell your doctor if you notice any of the following symptoms:**
 - weight gain
 - roundness of face
 - acne
 - a tendency to bruise easily

Call your doctor straight away if you:

- are taking Cipla Budesonide + Formoterol 200/6 for COPD and you notice any signs of pneumonia (infection of the lung). Signs include fever or chills, increased phlegm/sputum production or change in colour, increased cough or increased breathing difficulties. Pneumonia is a serious medical condition and will require urgent medical attention.

Remind any doctor, dentist or pharmacist you visit that you are using Cipla Budesonide + Formoterol 200/6.

Things you should not do

- Do not stop using this medicine suddenly without checking with your doctor.
- Do not take any other medicines for your asthma or COPD without checking with your doctor.
- Do not give Cipla Budesonide + Formoterol 200/6 to anyone else, even if they have the same condition as you.
- Do not use Cipla Budesonide + Formoterol 200/6 to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cipla Budesonide + Formoterol 200/6 affects you.

Cipla Budesonide + Formoterol 200/6 may cause dizziness, light-headedness, tiredness or drowsiness in some people when they first start using it.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Storage

Store below 25°C. Do not refrigerate or freeze. Protect from frost and direct sunlight.

Always replace the mouthpiece cover after using Cipla Budesonide + Formoterol 200/6.

Discard Cipla Budesonide + Formoterol 200/6 within 3 months after removal from the foil pouch.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

WARNING

The canister in Cipla Budesonide + Formoterol 200/6 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.

Cleaning

The Cipla Budesonide + Formoterol 200/6 mouthpiece must be wiped with a clean dry cloth/tissue and must never get wet.

Getting rid of any unwanted medicine

Since some medicine may remain inside your Cipla Budesonide + Formoterol 200/6 you should always return it to your pharmacist for disposal including:

- when you have taken all your doses and the dose counter is on zero ('0' – see instructions in the pack), or
- 3 months after removal from the foil pouch, or
- it is damaged or past its expiry date, or
- your doctor/pharmacist has told you to stop using it.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Cipla Budesonide + Formoterol 200/6.

If you get any side effects, do not stop using Cipla Budesonide + Formoterol 200/6 without first talking to your doctor or pharmacist.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Mouth/throat-related: <ul style="list-style-type: none"> • sore, yellowish, raised patches in the mouth (thrush) • hoarse voice • irritation of the tongue and mouth • coughing 	These are less likely to happen if you rinse your mouth out after every time you use your usual morning and/or evening dose of Cipla Budesonide + Formoterol 200/6. Speak to your doctor if you have any of these less serious side

	effects and they worry you.
Heart-related: <ul style="list-style-type: none"> fast or irregular heart rate or pounding heart chest pain Nervous system-related: <ul style="list-style-type: none"> feeling anxious, nervous, restless or upset headache trembling or shakiness feeling light-headed or dizzy thirsty unpleasant taste in your mouth tiredness Gut-related: <ul style="list-style-type: none"> nausea (feeling sick) diarrhoea Skin-related: <ul style="list-style-type: none"> skin rash skin bruising Others: <ul style="list-style-type: none"> difficulty sleeping muscle twitching or cramps weight gain 	Speak to your doctor if you have any of these less serious side effects and they worry you.
<ul style="list-style-type: none"> mood changes 	Speak to your doctor if you notice any of these. You may need urgent medical attention.

Serious side effects

Serious side effects	What to do
Allergic Reaction: <ul style="list-style-type: none"> difficulty breathing or worsening of your breathing problems swelling of the face, lips, tongue or other parts of the body severe rash Pneumonia (lung infection): <ul style="list-style-type: none"> signs include fever or chills, increased phlegm/sputum production or a change in colour, increased cough or difficulties breathing 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. You may need urgent medical attention. Serious side effects are rare.
Potential eye problem: Any issues with your eyes such as	Speak to your doctor if you

blurred vision or other problems with your eyesight.	notice any of these. Your doctor may need to send you to an ophthalmologist (eye doctor) to check that you don't have eye problems such as cataracts (clouding of the eye lens), glaucoma (increased pressure in your eyeballs) or other rare eye conditions reported with corticosteroids use.
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Other side effects

Growth

Corticosteroids taken into the lungs for long periods (eg 12 months) may affect how children/adolescents grow. In rare cases, some children/adolescents may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a child's/adolescent's height.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (for example, changes in blood sugars) can only be found when your doctor does test from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Cipla Budesonide + Formoterol 200/6 contains

Active ingredients (main ingredient)	<ul style="list-style-type: none">• budesonide• formoterol fumarate dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• apaflurane• macrogol 1000• povidone

Do not take this medicine if you are allergic to any of these ingredients.

Cipla Budesonide + Formoterol 200/6 does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What Cipla Budesonide + Formoterol 200/6 looks like

Cipla Budesonide + Formoterol 200/6 is a pressurised metered dose inhaler with a dose counter. The inhaler is comprised of aluminium canister with a suitable metering valve fitted in a white polypropylene actuator with a dose counter and brown dust cap. Each inhaler is individually wrapped in a foil laminate pouch containing a drying agent.

Cipla Budesonide + Formoterol 200/6 is available in pack containing 1 inhaler of 120 inhalations of the medicine.
[AUST R 437652]

Who distributes Cipla Budesonide + Formoterol 200/6

Cipla Australia Pty Ltd.,
Level 1, 132-136 Albert Road,
South Melbourne, VIC 3205.
drugsafety@cipla.com
Toll Free number: 1800 569 074

This leaflet was prepared in February 2025.