

DUORESP® SPIROMAX®

Budesonide and formoterol (eformoterol) fumarate dihydrate powder for inhalation

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DuoResp Spiromax. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using DuoResp Spiromax 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 your DuoResp Spiromax.

You may need to read it again.

What DuoResp Spiromax is used for

DuoResp Spiromax is inhaled into the lungs for the treatment of asthma or Chronic Obstructive Pulmonary Disease (COPD).

DuoResp Spiromax contains two active ingredients in one inhaler: budesonide and formoterol (eformoterol) fumarate dihydrate (hereafter referred to as formoterol).

- 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.

ASTHMA

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

DuoResp Spiromax contains budesonide and formoterol in one inhaler.

Budesonide helps to improve your condition and to prevent asthma attacks from occurring. It is a "preventer" and needs to be taken regularly.

Formoterol helps you breathe more easily. It should also be taken regularly to help control your symptoms.

Budesonide and formoterol in combination, when used regularly, will help prevent asthma attacks and make it easier to breathe normally.

DuoResp Spiromax can also be used as a "reliever" when needed to treat your symptoms when your asthma gets worse and when used regularly will 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.

When used as prescribed, DuoResp Spiromax will help to control your COPD symptoms (i.e. breathing difficulties)

Ask your doctor if you have any questions about why DuoResp Spiromax has been prescribed for you.

Your doctor may have prescribed it for another reason. The active substances in DuoResp Spiromax (budesonide and formoterol) are not addictive.

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

Before you use DuoResp Spiromax

When you must not use it

Do not use DuoResp Spiromax if you have an allergy to:

- any medicine containing formoterol or budesonide
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

Do not give DuoResp Spiromax to a child or adolescent under 18 years.

Do not use DuoResp Spiromax after the expiry date (EXP) 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.

Before you start to use it

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

Your doctor should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have sudden attacks of asthma.

Your doctor may have prescribed DuoResp for you to use as both a "preventer" and "reliever" medicine.

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

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

- thyroid or adrenal gland problems
- diabetes
- heart problems
- liver problems
- tuberculosis (TB)
- low levels of potassium in the blood

It may not be safe for you to take DuoResp Spiromax if you have, or have had, any of these conditions.

Tell your doctor if you currently have an infection.

If you take DuoResp Spiromax 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.

Tell your doctor if you are pregnant or intend to become pregnant or breastfeeding.

Your doctor will discuss the possible risks and benefits of using DuoResp Spiromax during pregnancy and while breastfeeding.

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

Taking other medicines

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

Some medicines and DuoResp Spiromax may interfere with each other. 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 (e.g. ketoconazole, itraconazole, voriconazole))
- xanthine derivatives (e.g. theophylline) which are a class of medicines used to treat asthma and COPD.
- Medicines like digoxin used to treat heart failure
- Medicines used to treat HIV infection
- Medicines for Parkinson's disease (e.g. L-dopa)

- Medicines for thyroid problems (e.g. thyroxine)

These medicines may be affected by DuoResp Spiromax, 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.

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

How to use DuoResp Spiromax

How to use your device

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

They may differ from the information contained in this leaflet.

Each pack of DuoResp Spiromax contains an instruction leaflet that tells you the correct way to use it. Please read this carefully.

If you are not sure how to use the device, ask your doctor or pharmacist to show you how.

How much to take

ASTHMA (Adults only)

Your doctor should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have a sudden attack of asthma. Your doctor may have prescribed DuoResp for you to use as both a "preventer" and "reliever" medicine.

DuoResp Spiromax 200/6

If you are using DuoResp Spiromax 200/6 as a "preventer" medicine, the usual dose is 1 - 2 inhalations twice a day.

Your doctor may also tell you to use DuoResp Spiromax as a "reliever", medication. This means that DuoResp Spiromax can be used when needed to provide relief of your asthma symptoms. If you are using DuoResp Spiromax 200/6 as both a "preventer" and "reliever" medicine, 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 three days, despite using additional inhalations, tell your doctor.

DuoResp Spiromax 400/12

DuoResp Spiromax 400/12 is not recommended to be used as a "reliever" medication.

The usual dose is 2 inhalations twice a day. Your doctor may also tell you to take 1 inhalation twice a day, if your asthma has been under control.

Do not take more than 2 inhalations twice a day of DuoResp Spiromax 400/12.

If your asthma has been under control for some time, your doctor may tell you to take less inhalations of DuoResp Spiromax or prescribe you a lower strength of DuoResp Spiromax.

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.

COPD (Adults)

The usual dose (also maximum recommended dose) is:

- 2 inhalations of DuoResp Spiromax 200/6 twice daily or
- 1 inhalation of DuoResp Spiromax 400/12 twice daily.

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).

If you forget to use it

If you miss a dose of DuoResp Spiromax, 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 DuoResp Spiromax as a "reliever" medication, 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.

How long to use it

Use DuoResp Spiromax every day even if you feel well.

DuoResp Spiromax 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.

If you take too much (overdose)

Telephone your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much DuoResp Spiromax.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you use too much DuoResp Spiromax, 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

While you are using DuoResp Spiromax

How to use your Spiromax

If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.

Keep using DuoResp Spiromax 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 DuoResp Spiromax (200/6) or another "reliever" medication.

Rinse your mouth out with water after taking your regular morning and/or evening dose of DuoResp and spit this out.

If you don't you are more likely to develop thrush in your mouth. You do not have to rinse your mouth if you have to take occasional extra doses of DuoResp for relief of asthma symptoms.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using DuoResp Spiromax.

If you become pregnant while using DuoResp Spiromax, tell your doctor.

Things you must not do

Do not take any other medicines for your asthma or COPD without checking with your doctor.

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

Do not use DuoResp Spiromax to treat any other complaints unless your doctor tells you to.

Do not stop using DuoResp Spiromax without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how DuoResp affects you.

DuoResp Spiromax may cause dizziness, light-headedness, tiredness or drowsiness in some people when they first start using it.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using DuoResp Spiromax.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

If you get any side effects, do not stop using DuoResp Spiromax without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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 DuoResp Spiromax.

- trembling or shakiness
- feeling anxious, nervous, restless or upset
- fast or irregular heart rate or pounding heart
- chest pain
- headache
- feeling light-headed or dizzy
- thirsty
- unpleasant taste in your mouth
- nausea (feeling sick)
- diarrhoea
- difficulty sleeping
- muscle twitching or cramps
- skin rash
- tiredness
- weight gain
- skin bruising

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following as they could be symptoms of a lung infection (pneumonia):

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Tell your doctor or pharmacist immediately if you notice any of the following:

- difficulty breathing or worsening of your breathing problems
- swelling of the face, lips, tongue or other parts of the body
- severe rash
- mood changes

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

Other side effects not listed above may occur in some patients.

Some of these side effects (for example, changes in blood sugars)

can only be found when your doctor does tests from time to time to check your progress.

Corticosteroids taken into the lungs for long periods (e.g. 12 months) may affect growth. In rare cases, some patients may be sensitive to the growth effects of corticosteroids, so the doctor may monitor a patient's height.

After using DuoResp Spiromax

Cleaning

Keep your Spiromax device dry and clean. If necessary, you may wipe the mouthpiece of your Spiromax device after use with a dry cloth or tissue.

Full instructions on the right way to use and clean DuoResp Spiromax are inside each pack.

Storage

Keep your Spiromax in a cool dry place where the temperature stays below 25°C, with the cover firmly in place.

Do not store DuoResp Spiromax or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Since some medicine may remain inside your DuoResp Spiromax you should always return it to your pharmacist for disposal including:

- **when you have taken all your doses and the dose indicator is on zero ('0' - see instructions in the pack), or**

- **if it is damaged or past its expiry date, or**
- **if it has been removed from the foil wrapping for greater than 6 months, or**
- **if your doctor/pharmacist has told you to stop using it.**

This leaflet was prepared
July 2017

Australian Registration Numbers

200/6 - AUST R 267385

400/12 - AUST R 267386

® DuoResp and Spiromax are
registered trademarks of the Teva
group of companies.

Product description

What it looks like

DuoResp Spiromax is a plastic inhaler containing the medication as a dry powder. The Spiromax device is white in colour, with a semi-transparent wine red mouthpiece cover at the bottom.

DuoResp Spiromax 200/6 is registered in packs of 1, 2 or 3 inhalers. Each DuoResp Spiromax 200/6 inhaler contains 120 inhalations.

DuoResp Spiromax 400/12 is registered in packs of 1, 2 or 3 inhalers. Each DuoResp Spiromax 400/12 inhaler contains 60 inhalations.

Not all pack sizes may be marketed.

Ingredients

DuoResp Spiromax contains budesonide and formoterol (eformoterol) fumarate dihydrate as the active ingredients, and lactose (which may contain milk protein residue).

The amount of lactose contained in DuoResp Spiromax is very small and does not normally cause problems in lactose intolerant people.

DuoResp Spiromax does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Teva Pharma Australia Pty Ltd
37 Epping Road
MACQUARIE PARK NSW 2113