

OXIS® TURBUHALER®

Formoterol fumarate dihydrate for inhalation

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Oxis Turbuhaler. 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 Oxis Turbuhaler 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 Oxis Turbuhaler.

You may need to read it again.

What Oxis Turbuhaler is used for

The active ingredient in Oxis Turbuhaler is inhaled into the lungs for the treatment of 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.

Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough.

Oxis Turbuhaler contains the active ingredient formoterol fumarate dihydrate (previously known as eformoterol fumarate dihydrate). Formoterol is a bronchodilator and belongs to a group of medicines called beta-2-agonists.

Oxis Turbuhaler opens up the airways in people with asthma so that they can breathe more easily. Oxis Turbuhaler will start to work soon after you take it and the effects will last up to 12 hours. It should be taken regularly to help control your symptoms. It may also be used if you have difficulty breathing at night or before exercise to keep your airways open if you start to wheeze or have difficulty breathing each time you exert yourself.

In patients already taking regular Oxis Turbuhaler, it can also be used when needed to treat your symptoms when your asthma control gets worse.

Oxis Turbuhaler is used together with other regular preventer medicines called inhaled corticosteroids (ICS).

Ask your doctor if you have any questions about why Oxis Turbuhaler has been prescribed for you.

Your doctor may prescribe it for another reason.

Oxis Turbuhaler is not addictive

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

Before you use Oxis Turbuhaler

When you must not use it

Do not use Oxis Turbuhaler if you have an allergy to:

- any medicine containing formoterol
- lactose (the only inactive ingredient in Oxis Turbuhaler)

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 Oxis Turbuhaler to a child under 12 years, unless directed to by the child's doctor.

Oxis Turbuhaler is not recommended for use in children under 12 years.

Do not use Oxis Turbuhaler 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 Oxis Turbuhaler, talk to your doctor or pharmacist.

Before you start to use it

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 (eg preventer and controller medicines), as well as what reliever medicines to use when you have sudden attacks of asthma. Your doctor may have prescribed Oxis Turbuhaler for you to use as a regular controller and as a 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 problems
- diabetes
- heart problems
- liver problems
- low levels of potassium in the blood.

It may not be safe for you to use Oxis Turbuhaler if you have or have had any of these conditions.

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 Oxis Turbuhaler 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 Oxis Turbuhaler.

Taking other medicines

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

Some medicines and Oxis Turbuhaler may interfere with each other. These include:

- medicines for heart problems or high blood pressure such as beta-blockers, diuretics and antiarrhythmics (disopyramide, procainamide and quinidine)
- medicines for glaucoma (including eye drops) such as beta-blockers
- medicines for depression or other mood/mental disorders such as tricyclic antidepressants, monoamine oxidase inhibitors and phenothiazines
- medicines for hayfever, coughs, colds and runny nose such as antihistamines
- erythromycin (an antibiotic)
- xanthine derivatives (eg theophylline) which are a class of medicines used to treat

asthma and chronic obstructive airways disease

These medicines may be affected by Oxis Turbuhaler, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using Oxis Turbuhaler.

How to use Oxis Turbuhaler

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 Oxis Turbuhaler 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 Turbuhaler, ask your doctor or pharmacist.

Oxis Turbuhaler can be used regularly to prevent asthma attacks (ie maintenance treatment). It can also be used when needed to treat your symptoms when your asthma control gets worse.

How much to use

Please note that Oxis Turbuhaler is labelled as the metered dose (amount of the active ingredient from the meter inside the mouthpiece of the original version). The delivered dose (amount of active ingredient from the mouthpiece) is also included on the label. The doses below are metered doses with the corresponding delivered dose in brackets.

Regular maintenance treatment

The usual maintenance dose is one inhalation of Oxis Turbuhaler (6 mcg [4.5 mcg] or 12 mcg [9 mcg])

twice a day. Some patients may need to take 2 inhalations twice a day.

For adults, the maintenance dose should not exceed:

- 4 inhalations of Oxis Turbuhaler 6 mcg [4.5 mcg] twice a day, or
- 2 inhalations of Oxis Turbuhaler 12 mcg [9 mcg] twice a day

For children 12 years and over, the maintenance dose should not exceed:

- 2 inhalations of Oxis Turbuhaler 6 mcg [4.5 mcg] twice a day, or
- 1 inhalation of Oxis Turbuhaler 12 mcg [9 mcg] twice a day

As-needed use (to relieve asthma symptoms) for adults over 18 years

In addition to your maintenance dose, your doctor may advise you to take additional doses, if necessary, to relieve your asthma symptoms.

If you are using Oxis Turbuhaler for both maintenance treatment and as-needed use (to relief of asthma symptoms), the total daily dose should not exceed:

- 12 inhalations per day of Oxis Turbuhaler 6 mcg [4.5 mcg], or
- 6 inhalations per day of Oxis Turbuhaler 12 mcg [9 mcg]

Tell your doctor if your symptoms continue to worsen over three days, despite using more than:

- 8 inhalations per day of Oxis Turbuhaler 6 mcg [4.5 mcg], or
- 4 inhalations per day of Oxis Turbuhaler 12 mcg [9 mcg]

As-needed use is not recommended for patients under the age of 18 years.

How long to use it

Continue using Oxis Turbuhaler for as long as your doctor tells you.

Oxis Turbuhaler helps to control your condition, but does not cure it. It is important to keep using Oxis Turbuhaler every day even if you feel well.

If you forget to use it

If it is almost time for your next maintenance dose, skip the dose you missed and use the next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

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 not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Oxis Turbuhaler.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you use too much Oxis Turbuhaler you may feel sick or vomit, have a fast or irregular heartbeat, a headache, trembling or feel shaky.

While you are using Oxis Turbuhaler

Things you must do

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

Have your reliever medicine available at all times.

Continue using Oxis Turbuhaler and your preventer medicine for as long as your doctor or pharmacist tells you.

Oxis Turbuhaler should be used with a preventer medicine, even if you feel that your symptoms have improved.

If you find that the usual dose of Oxis Turbuhaler is not giving as much relief as before, or you are needing to use it more often, contact your doctor so that your condition can be checked.

This is important to ensure that your breathing problem is controlled properly.

Visit your doctor regularly to check your asthma condition.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Oxis Turbuhaler.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Oxis Turbuhaler.

If you become pregnant while using Oxis Turbuhaler, tell your doctor or pharmacist.

Things you must not do

Do not stop using Oxis Turbuhaler without checking with your doctor or pharmacist.

Do not stop taking any other medicines you have been given for your asthma, even if you are feeling better, without checking with your doctor first.

Oxis Turbuhaler is intended to be used with preventer medicines.

Do not use other medicines that contain long-acting beta-2-agonists such as salmeterol, when you are taking Oxis Turbuhaler.

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

Do not use Oxis Turbuhaler to treat any other complaints unless your doctor tells you to.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are using Oxis Turbuhaler.

Oxis Turbuhaler helps most people with asthma, 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 treatment 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 if you notice any of the following and they worry you:

- tremor
- muscle cramps
- agitation, restlessness
- sleep disturbances
- headache, dizziness
- palpitations, fast/irregular heart rate
- chest pain
- nausea
- taste disturbances
- skin rash
- changes in blood pressure

These side effects are usually mild.

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

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

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

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

Some side effects (e.g. low potassium levels in the blood or

increase in blood sugar levels) may only be found when your doctor does tests from time to time to check your progress.

After using Oxis Turbuhaler

Cleaning

The Turbuhaler must be wiped with a clean dry tissue and must never get wet.

Full instructions on the right way to use and clean Oxis Turbuhaler are inside each pack.

Storage

Keep your Oxis Turbuhaler in a cool, dry place where the temperature stays below 30°C, with the cover firmly in place.

Do not store Oxis Turbuhaler or any other medicine in the bathroom or near a sink.

Do not leave it in the car 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 Oxis Turbuhaler 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')**
- **it is damaged or past its expiry date, or**
- **your doctor/pharmacist has told you to stop using it.**

Product description

What it looks like

Oxis Turbuhaler is a multidose, breath activated metered dose dry powder inhaler containing 60 doses of formoterol fumarate dihydrate.

Turbuhaler is made up of plastic parts.

Ingredients

Oxis Turbuhaler contains formoterol fumarate dihydrate (previously known as eformoterol fumarate dihydrate) as the active ingredient, and lactose monohydrate (which may contain milk protein residue).

Supplier

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone: 1800 805 342

This leaflet was prepared 26 October 2020

Australian Registration Numbers:

Oxis Turbuhaler (delivered dose provided in brackets)

6 mcg (4.5 mcg) - AUST R 60142

12 mcg (9 mcg) - AUST R 60141

® Oxis and Turbuhaler are registered trade marks of the AstraZeneca group of companies.

© AstraZeneca, 2020

Doc ID-000184514 v6