

OXIS® TURBUHALER®

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 Oxis Turbuhaler?

Oxis Turbuhaler contains the active ingredient formoterol fumarate dihydrate. Oxis Turbuhaler is inhaled into the lungs and opens up the airway in people with asthma so that they can breathe more easily. For more information, see Section [1. Why am I using Oxis Turbuhaler?](#) in the full CMI.

2. What should I know before I use Oxis Turbuhaler?

Do not use if you have ever had an allergic reaction to any medicine containing formoterol, or lactose 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 Oxis Turbuhaler?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Oxis Turbuhaler 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 Oxis Turbuhaler?

- Oxis Turbuhaler should be inhaled into your lungs through the mouth.
- 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.
- Follow all directions given to you by your doctor or pharmacist.

More instructions can be found in Section [4. How do I use Oxis Turbuhaler?](#) in the full CMI.

5. What should I know while using Oxis Turbuhaler?

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.• Continue using Oxis Turbuhaler and your preventer medicine for as long as your doctor or pharmacist tells you.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly 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.• Do not use other medicines that contain long-acting beta-2-agonists such as salmeterol, when you are taking Oxis Turbuhaler.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Turbuhaler in a cool dry place where the temperature stays below 30°C, with the cover firmly in place.• The Turbuhaler mouthpiece must be wiped with a clean dry cloth/tissue and must never get wet.

For more information, see Section [5. What should I know while using Oxis Turbuhaler?](#) 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 tremor, muscle cramps, agitation, sleep disturbances, headache, fast/irregular heart rate, chest pain, nausea or taste disturbances. However, some side effects may need medical attention. These include severe allergic reactions such as difficulty breathing, swelling of the face, lips or tongue or severe rash. 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.

OXIS® TURBUHALER®

Active ingredient(s): *formoterol fumarate dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Oxis Turbuhaler. **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 Oxis Turbuhaler.**

Where to find information in this leaflet:

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

1. Why am I using Oxis Turbuhaler?

Oxis Turbuhaler contains the active ingredient **formoterol fumarate dihydrate**. Formoterol is a bronchodilator and belongs to a group of medicines called beta-2-agonists.

Oxis Turbuhaler is inhaled into the lungs and opens up the airway 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).

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 or air pollution or other things that irritate your lungs.

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

The formoterol in Oxis Turbuhaler helps you breathe more easily.

2. What should I know before I use Oxis Turbuhaler

Warnings

Do not use Oxis Turbuhaler if:

- you are allergic to any medicine containing formoterol, or lactose (the only inactive ingredient in Oxis Turbuhaler). 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, foods, preservations or dyes.
- have, or have had, any of the following medical conditions, as it may not be safe for you to take Oxis Turbuhaler:
 - thyroid problems
 - diabetes
 - heart problems
 - liver problems
 - low levels of potassium in the blood.
- have any other medical conditions.
- have any questions about how you should be using your Oxis Turbuhaler.

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 Oxis Turbuhaler during pregnancy and while breastfeeding.

Children

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.

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 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.

3. What if I am taking other medicines?

Some medicines may interfere with Oxis Turbuhaler 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 (including eye drops) 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
- 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 medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

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 including vitamins or supplements. Check with your doctor if you are not sure.

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

4. How do I use Oxis Turbuhaler?

How to use your 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 for use 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 to show you how.

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 take

Please note that Oxis Turbuhaler is labelled as the metered dose (amount of 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 inhalations 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 your Oxis Turbuhaler

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

Oxis Turbuhaler helps 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 Oxis Turbuhaler

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 to use your medicine, ask your pharmacist for some hints.

If you use too much Oxis Turbuhaler

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

5. What should I know while using Oxis Turbuhaler?

Things you should 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.
- 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.

Remind any doctor, dentist or pharmacist you visit that you are using Oxis Turbuhaler.

Things you should not do

- Do not stop using Oxis Turbuhaler suddenly 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.

Looking after your medicine

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

Storage

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

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.

Cleaning

The Turbuhaler mouthpiece 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.

Getting rid of any unwanted medicine

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' – see instructions in the pack), or
- it is damaged or past its expiry date, or
- your doctor/pharmacist have told you to stop using it.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you get any side effects, do not stop using Oxis Turbuhaler 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. Do not be alarmed by the following lists of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">tremormuscle crampsagitation, restlessnesssleep disturbancesheadache, dizzinesspalpitations, fast/irregular heart ratechest painnauseataste disturbancesskin rashchanges in blood pressure	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic Reaction: <ul style="list-style-type: none">difficulty breathing or worsening of your breathing problemsswelling of the face, lips, tongue or other parts of the bodysevere rash	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.

Other side effects

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, 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.

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 Oxis Turbuhaler contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">formoterol fumarate dihydrate
Other ingredients (inactive ingredients)	Lactose monohydrate
Potential allergens	Lactose (which may contain milk protein residue)

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

What Oxis Turbuhaler looks like

Oxis Turbuhaler is a multidose, breath activated metered dose dry powder inhaler. Turbuhaler is made up of plastic parts.

Oxis Turbuhaler is registered in the following presentations*:

- 6 mcg: Each carton contains one Oxis Turbuhaler of 60 doses of the medicine. [AUST R 60142]
- 12 mcg: Each carton contains one Oxis Turbuhaler of 60 doses of the medicine. [AUST R 60141]

*not all registered presentations might be available in Australia

Who distributes Oxis Turbuhaler

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Telephone:- 1800 805 342

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