

PATIENT INFORMATION LEAFLET

Oxis Turbuhaler 4.5 mcg/dose & 9 mcg/dose

formoterol fumarate dihydrate

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What Oxis Turbuhaler is used for

Your doctor has prescribed this medicine to treat asthma or chronic obstructive pulmonary disease (COPD).

Asthma

For asthma, your doctor will prescribe two asthma inhalers: Oxis Turbuhaler and a separate 'corticosteroid' inhaler. These should be used together.

- Oxis Turbuhaler is used to help prevent asthma symptoms from happening.
- Some people also use Oxis Turbuhaler when they need extra doses for relief of asthma symptoms, to make it easier to breathe again.
- Oxis Turbuhaler can also be used before exercise to prevent asthma symptoms caused by exercise.

Chronic obstructive pulmonary disease (COPD)

Oxis Turbuhaler can also be used to treat the symptoms of COPD in adults. COPD is a long-term disease of the airways in the lungs, which is often caused by cigarette smoking.

How Oxis Turbuhaler works

Oxis Turbuhaler is an inhaler. It contains a medicine called formoterol. This belongs to a group of medicines called 'long-acting beta-agonists' or 'bronchodilators'.

It works by relaxing the muscles in your airways. This helps you to breathe more easily. It starts to work within 1 to 3 minutes and the effects last up to 12 hours.

Before you take Oxis Turbuhaler

When you must not take it

Do not use Oxis Turbuhaler if:

- You are allergic (hypersensitive) to formoterol, or the other ingredient, lactose (which contains small amounts of milk proteins).

Before you start to take it

Before you use Oxis Turbuhaler, tell your doctor or pharmacist if:

- You are diabetic. You may need some additional blood sugar tests while you are using Oxis Turbuhaler.

- You have high blood pressure or you have ever had a heart problem.
- You have problems with your thyroid gland.
- You have low levels of potassium in your blood. Your doctor may take blood samples to check the levels of potassium in your blood.
- You have severe liver problems such as liver cirrhosis.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Oxis Turbuhaler.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Oxis Turbuhaler can affect the way some medicines work and some medicines can have an effect on Oxis Turbuhaler.

In particular, tell your doctor or pharmacist if you are taking 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 asthma.
- Erythromycin (used to treat infections).
- Anti-histamines (such as terfenadine).
- Other substances that dilate the airways (bronchodilators, such as salbutamol).
- Ephedrine (used to treat asthma or as a decongestant).
- Tricyclic anti-depressants (such as amitriptyline).

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

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

The addition of anticholinergics (such as tiotropium or ipratropium bromide) to the treatment with Oxis Turbuhaler, can help to open your airways even more.

How to take Oxis Turbuhaler

How much & when to take

- Always use Oxis Turbuhaler exactly as your doctor, nurse or pharmacist has told you. Ask one of them for advice if you are not sure.
- Do not increase the dose of Oxis Turbuhaler prescribed by your doctor without talking to your doctor first.
- If you are using Oxis Turbuhaler regularly for asthma or COPD you should continue to use your medicine, even if you have no symptoms.

Important information about your asthma or COPD symptoms

If you feel you are getting breathless or wheezy while using Oxis Turbuhaler, you should continue to use Oxis Turbuhaler 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 with asthma.
- You start getting chest tightness.
- You are not getting relief from your current dose.
- You need to take more than your usual dose for more than two days in a week.
- You need to use your Turbuhaler more often than usual before exercise.

These signs could mean that your asthma or COPD is not being properly controlled and you may need different or additional treatment immediately.

Dosage for Oxis Turbuhaler 4.5 mcg/ dose

Asthma

Oxis Turbuhaler should not be used in children under 6 years of age.

Adults (18 years and above)

- The usual dose is 1 or 2 inhalations, once or twice a day.
- Your doctor may increase this to 4 inhalations, once or twice a day.
- Some people also use Oxis Turbuhaler as a 'reliever inhaler'. If you get asthma symptoms, the usual dose is 1 or 2 inhalations when they happen.
- A total daily dose of more than 8 inhalations is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise. However, your doctor may allow you to take up to 12 inhalations a day. Do not use more than 12 inhalations in total in 24 hours.
- Do not take more than 6 inhalations at any one time.

Children and adolescents (6 to 17 years)

- The usual dose is 2 inhalations, once or twice a day.
- Some children also use Oxis Turbuhaler as a 'reliever inhaler'. If your child gets asthma symptoms, the usual dose is 1 or 2 inhalations when they happen.
- A total daily dose of more than 4 inhalations is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. However, your doctor may allow your child to take up to 8 inhalations a day. Your child should not use more than 8 inhalations in total in 24 hours.
- Your child should not have more than 2 inhalations at any one time.

Asthma caused by exercise

If you or your child have asthma symptoms caused by exercise, your doctor may advise you or your child to use Oxis Turbuhaler before exercise as well. Oxis Turbuhaler should not be used in children under 6 years of age.

Adults (18 years and above)

- The usual dose is 2 inhalations before exercise.
- A total daily dose of more than 8 inhalations is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise. However, your doctor may allow you to take up to 12 inhalations a day. Do not use more than 12 inhalations in total in 24 hours.
- Do not take more than 6 inhalations at any one time.

Children and adolescents (6 to 17 years)

- The usual dose is 1 or 2 inhalations before exercise.
- A total daily dose of more than 4 inhalations is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. However, your doctor may allow your child to take up to 8 inhalations a day. Your child should not use more than 8 inhalations in total in 24 hours.
- Your child should not have more than 2 inhalations at any one time.

Chronic obstructive pulmonary disease (COPD)

- Only to be used by adults (aged 18 years and above).
- The usual dose is 2 inhalations once or twice a day.
- Your doctor may advise you to take extra doses for relief of your COPD symptoms.
- You should not have more than 8 inhalations a day.
- Do not take more than 4 inhalations at any one time.

Dosage for Oxis Turbuhaler 9 mcg/ dose

Asthma

Oxis Turbuhaler should not be used in children under 6 years of age.

Adults (18 years and above)

- The usual dose is 1 inhalation, once or twice a day.
- Your doctor may increase this to 2 inhalations, once or twice a day.
- Some people also use Oxis Turbuhaler as a 'reliever inhaler'. If you get asthma symptoms, the usual dose is 1 inhalation when they happen.
- A total daily dose of more than 4 inhalations is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise. However, your doctor may allow you to take up to 6 inhalations a day. Do not use more than 6 inhalations in total in 24 hours.
- Do not take more than 3 inhalations at any one time.

Children and adolescents (6 to 17 years)

- The usual dose is 1 inhalation once or twice a day.
- Some children also use Oxis Turbuhaler as a 'reliever inhaler'. If your child gets asthma symptoms, the usual dose is 1 inhalation when they happen.
- A total daily dose of more than 2 inhalations is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. However, your doctor may allow your child to take up to 4 inhalations a day. Your child should not use more than 4 inhalations in total in 24 hours.
- Your child should not have more than 1 inhalation at any one time.

Asthma caused by exercise

If you or your child have asthma symptoms caused by exercise, your doctor may advise you or your child to use Oxis Turbuhaler before exercise as well. Oxis Turbuhaler should not be used in children under 6 years of age.

Adults (18 years and above)

- The usual dose is 1 inhalation before exercise.
- A total daily dose of more than 4 inhalations is not normally needed. This includes the inhalations that you take every day, when you get asthma symptoms and before exercise.

However, your doctor may allow you to take up to 6 inhalations a day. Do not use more than 6 inhalations in total in 24 hours.

- Do not take more than 3 inhalations at any one time.

Children and adolescents (6 to 17 years)

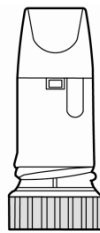
- The usual dose is 1 inhalation before exercise.
- A total daily dose of more than 2 inhalations is not normally needed. This includes the inhalations that your child takes every day, when they get asthma symptoms and before exercise. However, your doctor may allow your child to take up to 4 inhalations a day. Your child should not use more than 4 inhalations in total in 24 hours.
- Your child should not have more than 1 inhalation at any one time.

Chronic obstructive pulmonary disease (COPD)

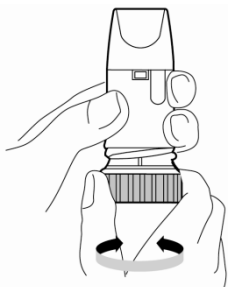
- Only to be used by adults (aged 18 years and above).
- The usual dose is 1 inhalation once or twice a day.
- Your doctor may advise you to take extra doses for relief of your COPD symptoms.
- You should not have more than 4 inhalations a day.
- Do not take more than 2 inhalations at any one time.

How to take an inhalation

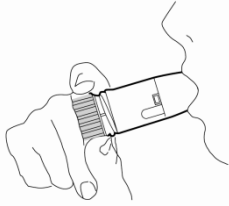
Every time you need to take an inhalation, follow the instructions below.



1. Unscrew the white cover and lift it off.
2. Hold your Turbuhaler upright with the turquoise grip at the bottom.
3. Do not hold the mouthpiece when you load your Turbuhaler. To load your Turbuhaler with a dose, turn the turquoise grip as far as it will go in one direction. Then turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should hear a click sound. Your Turbuhaler is now loaded and ready to use. It is not possible to overload your Turbuhaler even if you turn the grip several times. Only load your Turbuhaler when you need to use it.



4. Hold your Turbuhaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through your Turbuhaler.
5. Place the mouthpiece gently between your teeth. Close your lips. Breathe in as deeply and as hard as you can through your mouth. Do not chew or bite on the mouthpiece.



6. Remove your Turbuhaler from your mouth. Then breathe out gently. The amount of medicine that is inhaled is very small. This means you may not be able to taste it after inhalation. If you have followed the instructions, you can still be confident that you have inhaled the dose and the medicine is now in your lungs.
7. If you are to take a second inhalation, repeat steps 2 to 6.
8. Replace the cover tightly after use.

Do not try to remove or twist the mouthpiece. It is fixed to your Turbuhaler and must not be taken off. Do not use your Turbuhaler if it has been damaged or if the mouthpiece has come apart from your Turbuhaler.

Cleaning your Turbuhaler

Wipe the outside of the mouthpiece once a week with a dry tissue. Do not use water or liquids.

When to start using a new Turbuhaler

- The Turbuhaler contains 60 doses (inhalations). The dose indicator tells you how many doses are left in the Turbuhaler.
- When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. When the red mark reaches the bottom of the indicator window, you must start using your new Turbuhaler.



Note:

- The grip will still twist and 'click' even when your Turbuhaler is empty.
- The sound that you hear as you shake your Turbuhaler is produced by a drying agent and not the medicine. Therefore the sound does not tell you how much medicine is left in your Turbuhaler.

How long to take it

Do not stop using Oxis Turbuhaler without talking to your doctor.

If you have any further questions on using your Turbuhaler, ask your doctor, nurse or pharmacist.

If you forget to take it

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 take too much (overdose)

If you use more Oxis Turbuhaler than you should or, for instance a child has ingested the medicinal product by mistake, contact your doctor or pharmacist for advice immediately. The following effects may happen: trembling, headache or a rapid heart beat.

While you are using Oxis Turbuhaler

Things you must do

Use Oxis as directed by your doctor

Things you must not do

Do not stop using Oxis Turbuhaler unless advised by your doctor

Things to be careful of

Pregnancy and breast-feeding

- If you are pregnant, or planning to get pregnant, talk to your doctor before using Oxis Turbuhaler - do not use Oxis Turbuhaler unless your doctor tells you to.
- If you get pregnant while using Oxis Turbuhaler, do not stop using Oxis Turbuhaler but talk to your doctor immediately.
- If you are breast-feeding, talk to your doctor before using Oxis Turbuhaler.

Driving and using machines

Oxis Turbuhaler is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Oxis Turbuhaler

Oxis Turbuhaler contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

Side effects

Like all medicines, Oxis Turbuhaler can cause side effects, although not everybody gets them.

If the following happens to you, stop using Oxis Turbuhaler and talk to your doctor immediately:

- Bronchospasm (tightening of the muscles in the airways which causes sudden wheezing) after inhaling your medicine. This happens very rarely, affecting less than 1 in 10,000 people.

Other possible side effects:

Common (affects less than 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 Oxis Turbuhaler.
- Headache.

Uncommon (affects less than 1 in 100 people)

- Feeling restless or agitated.
- Disturbed sleep.
- Fast heart beat.
- Muscle cramps.

Rare (affects less than 1 in 1,000 people)

- Uneven heart beat.
- Nausea (feeling sick).
- Low level of potassium in your blood.
- Allergic reactions such as rash, itching and bronchospasm.

Very rare (affects less than 1 in 10,000 people)

- 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.
- Feeling dizzy.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storage and Disposal of Oxis Turbuhaler

Keep out of the reach and sight of children.

Do not store above 30°C.

When not in use, Oxis Turbuhaler should be stored with the cover tightened.

Do not use Oxis Turbuhaler after the expiry date printed on the carton or on the side of your Turbuhaler. The expiry date refers to the last day of that month.

Product description

Oxis Turbuhaler is an inhaler containing your medicine. The inhalation powder is white in colour. Each Turbuhaler contains 60 doses and has a white body with a turquoise turning grip.

Ingredients

The active substance is formoterol fumarate dihydrate.

In a Turbuhaler with 4.5 micrograms per dose, each dose contains 6 micrograms of formoterol fumarate dehydrate of which you can inhale 4.5 micrograms. In a Turbuhaler with 9 micrograms per dose, each dose contains 12 micrograms of formoterol fumarate dehydrate of which you can inhale 9 micrograms.

The other ingredient is lactose monohydrate (which contains milk proteins).

Malaysian registration numbers:

Oxis turbuhaler 4.5 mcg/dose: MAL19991002A

Oxis turbuhaler 9 mcg/dose: MAL19991003A

Manufacturer

AstraZeneca AB, 15185 Sodertalje, Sweden

Date of revision

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