

B. PACKAGE LEAFLET

Package Leaflet: Information for the user

Oxis Turbuhaler 9 micrograms per dose Inhalation Powder (Formoterol fumarate dihydrate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Oxis Turbuhaler is and what it is used for
2. What you need to know before you use Oxis Turbuhaler
3. How to use Oxis Turbuhaler
4. Possible side effects
5. How to store Oxis Turbuhaler
6. Contents of the pack and other information

1. What Oxis Turbuhaler is and what it is used for

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.

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

Asthma

Oxis Turbuhaler is used to treat asthma in adults, adolescents and children 6 years and older. 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.

2. What you need to know before you use Oxis Turbuhaler

Do not use Oxis Turbuhaler:

- If you are allergic (hypersensitive) to formoterol, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Oxis Turbuhaler 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.

Other medicines and Oxis Turbuhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 dilates 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.

Pregnancy, breast-feeding and fertility

- If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine - 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.

Driving and using machines

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

Oxis Turbuhaler contains lactose

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, contact your doctor before taking this medicinal product. 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.

3. How to use Oxis Turbuhaler

- Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist 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.

Asthma

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

Adults (18 years and above)

- The recommended 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 recommended 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.

Your doctor (or asthma nurse) will help you to manage your asthma. Once your asthma is well controlled your doctor may consider it appropriate to gradually reduce the dose of Oxis Turbuhaler.

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 recommended 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.
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Children and adolescents (6 to 17 years)

- The recommended 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 recommended 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.

Preparing your new Oxis Turbuhaler Inhaler

Before using your **new** Oxis Turbuhaler Inhaler **for the first time**, you need to prepare it for use as follows:

- Unscrew the cover and lift it off. You may hear a rattling sound.
- Hold your Oxis Turbuhaler Inhaler upright with the turquoise grip at the bottom.
- 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.
- Do this again, turning the turquoise grip in both directions.
- Your Oxis Turbuhaler Inhaler is now ready for use.

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. You may hear a rattling sound.
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. 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 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 the mouthpiece since it is fixed to your Turbuhaler and must not be taken off. The mouthpiece can be rotated but do not twist it unnecessarily. Do not use your Turbuhaler if it has been damaged or if the mouthpiece has come apart from your Turbuhaler.

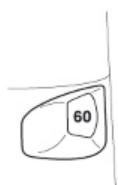
As with all inhalers, caregivers should ensure that children prescribed Oxis Turbuhaler use correct inhalation technique, as described above.

Cleaning your Turbuhaler

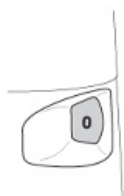
Wipe the outside of the mouthpiece once a week with a dry tissue. Do not use water or liquids.

When to start using a new Turbuhaler

- The dose indicator tells you how many doses are left in the Turbuhaler, starting with 60 doses when it is full.



- The dose indicator is marked in intervals of 10 doses. Therefore, it does not show every dose. When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last 10 doses, the background of the dose indicator is red. When the '0' on the red background has reached the middle of the window, you must start using a 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.
- If you load your Oxis Turbuhaler more than once by mistake before taking your dose, you will still only receive one dose. However, the dose indicator will register all the loaded doses.

If you use more Oxis Turbuhaler than you should

If you use more Oxis Turbuhaler than you should, contact your doctor or pharmacist for advice immediately. The following effects may happen: trembling, headache or a rapid heart beat.

If you forget to use Oxis Turbuhaler

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 stop using Oxis Turbuhaler

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.

4. Possible side effects

Like all medicines, this medicine 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, may affect up to 1 in 10,000 people.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Trembling or shaking. If these effects occur, they are usually mild and usually disappear as you continue to use Oxis Turbuhaler.
- Headache.
- Feeling dizzy.
- Nausea (feeling sick).
- Muscle cramps.

Uncommon (may affect up to 1 in 100 people)

- Palpitations (awareness of your heart beating). If this effect occurs, it is usually mild and usually disappears as you continue to use Oxis Turbuhaler.
- Disturbed sleep.
- Fast heart beat.
- Allergic reactions such as rash, itching and bronchospasm.
- Low level of potassium in your blood.
- 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.
- Uneven heart beat.
- Chest pain or tightness in the chest (angina pectoris).

Rare (may affect up to 1 in 1,000 people)

- Feeling restless or agitated.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxis Turbuhaler

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- When not in use, Oxis Turbuhaler should be stored with the cover tightened.
- Do not use this medicine after the expiry date which is stated on the carton or on the side of your Turbuhaler. The expiry date refers to the last day of that month.
- Always be sure to dispose of your used Turbuhaler responsibly, since some of the medicine will remain inside it. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Oxis Turbuhaler contains

The active substance is formoterol fumarate dihydrate. Each dose contains 12 micrograms of formoterol fumarate dihydrate of which you can inhale 9 micrograms.

The other ingredient is lactose monohydrate (which contains milk proteins). See section 2 Oxis Turbuhaler contains lactose.

What Oxis Turbuhaler looks like and contents of the pack

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.

Oxis Turbuhaler is available in the following pack sizes: 60 doses (1 inhaler), 3x60 doses (3 inhalers), 10x60 doses (10 inhalers), 18x60 doses (18 inhalers) or 20x60 doses (20 inhalers).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

For Sweden (RMS):
AstraZeneca AB
SE-151 85 Södertälje
Sweden

Manufacturer

AstraZeneca AB
Forskargatan 18
SE-151 36 Södertälje
Sweden

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Oxis Turbohaler 12 µg – Dosier - Pulverinhalator
Belgium	Oxis Turbohaler 9 µg/dose
Denmark	Oxis Turbuhaler
Finland	Oxis Turbuhaler
Germany	Oxis Turbohaler 12 Mikrogramm Pulver zur Inhalation
Greece	Oxez Turbuhaler
Ireland	Oxis Turbohaler 12, inhalation powder
Italy	Oxis Turbohaler 9
Luxembourg	Oxis Turbohaler 9 µg/dose
The Netherlands	Oxis 12 Turbuhaler
Portugal	Oxis Turbohaler
Spain	Oxis Turbuhaler 9 microgramos polvo para inhalación
Sweden	Oxis Turbuhaler
UK	Oxis Turbohaler 12, inhalation powder

This leaflet was last revised in September 2023.

[To be completed nationally]

Other sources of information

Detailed information on this medicine is available on the web site of: {name of MS/Agency}