

Oxis[®] 6 Turbuhaler

Eformoterol fumarate, 4.5 micrograms per delivered dose
(corresponding to 6 µg metered dose)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Oxis 6 Turbuhaler**. It does not contain all the information that is known about **Oxis 6 Turbuhaler**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Oxis 6 Turbuhaler** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Oxis is used for

Oxis 6 Turbuhaler relieves or prevents shortness of breath and other symptoms in patients with asthma and similar diseases. You usually notice an effect of **Oxis 6 Turbuhaler** within 1-3 minutes. The effect of one dose lasts for 12 hours. **Oxis 6 Turbuhaler** widens the airways which makes it easier to breathe. When you breathe in through the mouthpiece of the inhaler your breath carries the medicine to your lungs.

A short-acting bronchodilator should be used when you feel any acute symptoms. **Oxis 6 Turbuhaler** should be taken regularly together with other regular "preventer" medicines called corticosteroids.

Oxis 6 Turbuhaler contains the active ingredient eformoterol fumarate dihydrate. Eformoterol is a bronchodilator and belongs to a group of medicines called beta-2-agonists.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Oxis 6 Turbuhaler is not addictive.

Oxis 6 Turbuhaler is available only with a doctor's prescription.

Before you use Oxis 6 Turbuhaler

When you must not use it

Do not use **Oxis 6 Turbuhaler** if you have an allergy to:

- any medicine containing eformoterol
- lactose

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 use Oxis 6 Turbuhaler if you are pregnant or breast feeding unless your doctor says to do so. Ask your doctor about the risks and benefits involved. Tell your doctor if you intend to become pregnant. We do not know if your baby can take in **Oxis 6 Turbuhaler** from breast milk if you are breast feeding.

Do not use after the use by (expiry) date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you use it after the expiry date. **Do not use Oxis 6 Turbuhaler if the packaging is torn or shows signs of tampering.**

Do not use it to treat any other complaints unless your doctor tells you to. Do not give this medicine to anyone else.

Before you start to use it**You must tell your doctor if:****1. you have any allergies to**

- eformoterol or lactose
- any other substances ie other medicines, foods, preservatives or dyes.

2. you have any of these medical conditions

- thyroid problems
- diabetes
- any heart problems
- liver problems
- problems with your potassium levels.

It may not be safe for you to take **Oxis 6 Turbuhaler** if you have any of these conditions.

Taking other medicines**You must tell your doctor if you are taking any other medicines, including**

- medicines used to treat heart problems or high blood pressure
- medicines used to treat mood disorders, including depression
- medicines for glaucoma, including eye drops
- other medicines you are taking for your airway disease
- antibiotics (erythromycin)
- antihistamines
- any other medicine that you buy at the chemist, supermarket or health food shop.

These medicines may be affected by **Oxis 6 Turbuhaler**, or may affect how well it works.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you take Oxis 6 Turbuhaler.

Special warnings

You must contact your doctor as soon as possible if you need to use your rescue medicine inhaler more often than usual to control your airway disease. **Do not increase the dose of Oxis 6 Turbuhaler without talking to your doctor.** Always carry your rescue medicine with you.

If you experience an immediate increase in wheezing or shortness of breath after taking **Oxis 6 Turbuhaler** contact a doctor immediately.

Using Oxis 6 Turbuhaler**How to take it**

Your doctor will have explained why you are being treated with **Oxis 6 Turbuhaler** and told you what dose to take. **Follow all directions given to you by your doctor carefully.** They may differ from the information contained in this leaflet.

Each pack of **Oxis 6 Turbuhaler** contains an instruction leaflet that tells you the correct way to use it. **Please read this carefully.**

How much to takeAdults

The normal dose is 1-2 inhalations once or twice daily. **Do not take more than 8 inhalations in any 24 hour period.**

Children 6 years and older

The normal dose is 1-2 inhalations once or twice daily. **Do not inhale more than 4 inhalations in any 24 hour period.**

Adults and children 6 years and older for prevention of symptoms caused by exercise

1-2 inhalations in the morning or before exercise. **Oxis 6 Turbuhaler** will start to work soon after you take it and will last for 12 hours.

Things you must do

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

Continue using **Oxis 6 Turbuhaler** and your 'preventer' medicine for as long as your doctor or pharmacist tells you. **Oxis 6 Turbuhaler** should be used with a 'preventer' medicine, even if you feel that your symptoms have improved. You must contact your doctor as soon as possible if you need to use your 'reliever' (short-acting bronchodilator) more often than usual to relieve your breathing problems. You may need extra medication to control your asthma.

Do not increase the dose of Oxis 6 Turbuhaler without talking to your doctor. This is most important to make sure that your breathing problem does not get out of control.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using **Oxis 6 Turbuhaler**.

If you are about to start any new medicine, tell your doctor or pharmacist that you are using **Oxis 6 Turbuhaler**.

If you become pregnant while using **Oxis 6 Turbuhaler**, tell your doctor or pharmacist.

Things you must not do

Do not stop taking the other medicines you have been given for your asthma, even if you are feeling better, without checking with your doctor first. **Oxis 6 Turbuhaler** is intended to be used with 'preventer' medicines.

Do not give **Oxis 6 Turbuhaler** to anyone else, even if they have the same condition as you.

Do not use **Oxis 6 Turbuhaler** to treat any other complaints unless your doctor tells you to.

If you forget to take it

If you miss a dose you should take it as soon as you remember, as long as it is more than 6 hours before your next dose is due. If it is less than six hours, and if you feel you need a dose of Oxis 6 Turbuhaler, take the next dose early. Do not double the dose.

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

Overdose

Telephone your doctor or the National Poisons Centre Ph: 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Oxis 6 Turbuhaler, even if there are no signs of discomfort or poisoning.

If you take too much **Oxis 6 Turbuhaler** you may experience:

- trembling
- headache
- rapid heartbeat
- dizziness or unusual drowsiness

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Oxis 6 Turbuhaler. Ask them to answer any questions you may have.

Side effects that occur are usually mild and disappear by themselves within one or two weeks. Be sure to contact your doctor if any of the following side effects bother you or continue:

Common

- headache
- trembling
- dizziness
- nausea
- muscle cramps

Uncommon

- hypersensitivity reactions such as bronchospasm (cramp in the airways), skin rash
- changes in the salt balance in the blood (low potassium levels)
- high blood sugar levels
- rapid heartbeat
- sleep difficulties
- taste disturbances/ variations in the blood pressure
- irregular heartbeats
- chest pain

Rare

- mood changes

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

After using it***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 6 Turbuhaler** are inside each pack.

Storage

Keep your Oxis 6 Turbuhaler in a cool, dry place where the temperature stays below 30°C, with the cover firmly in place. Do not store it or any other medicine in the bathroom or near a sink. 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. **Do not leave it in the car on hot days.**

Disposal

Ask your pharmacist what to do with Oxis 6 Turbuhaler you have left over if your doctor tells you to stop taking it, or you find that the expiry date has passed.

Product description

Oxis 6 Turbuhaler is a multidose, breath activated metered dose dry powder inhaler containing 60 doses of eformoterol fumarate dihydrate. Turbuhaler is made up of plastic parts.

Ingredients

Oxis 6 Turbuhaler contains eformoterol fumarate dihydrate as the active ingredient as well as lactose.

Marketed by:

AstraZeneca Limited

P299 Private Bag 92175, Auckland 1142.

Telephone: (09) 306 5650.

Trademarks herein are property of the AstraZeneca Group.

© This CMI is copyrighted to AstraZeneca Limited and may be reproduced but not altered in any way.

2 March 2017