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Oxis Turbohaler advertisement.

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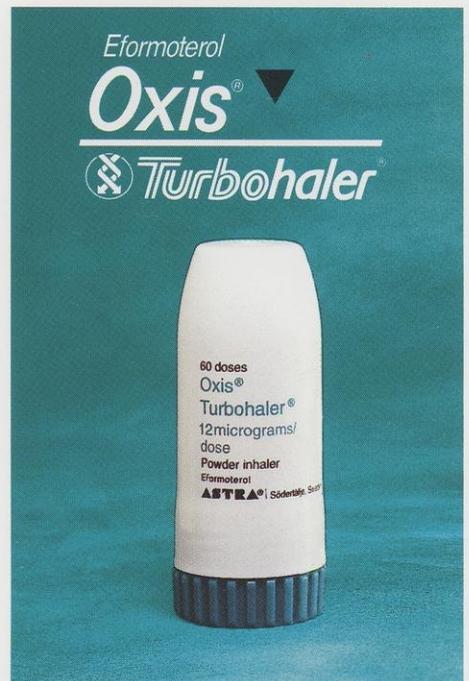


Oxis® Turbohaler® ▼ Long-lasting symptom relief – fast and easy

Oxis® Turbohaler® (efomedoterol) ▼ Prescribing Information
Oxis® Turbohaler® 6 and 12. **Presentation:** Dry powder inhaler containing either 6mcg or 12mcg efomedoterol fumarate dihydrate/actuation. **Uses:** The relief of broncho-obstructive symptoms in asthmatics when adequate treatment with corticosteroids is not sufficient. **Dosage & administration:** Adults (including the elderly): 6 or 12mcg once or twice daily in the morning and/or at night. Maximum daily dose is 48mcg. A single administration at night may be given in nocturnal asthma symptoms. Aim for the lowest effective dose. **Children:** No clinical experience. **Contra-indications, warnings etc:** Contra-indications: Hypersensitivity to efomedoterol or inhaled lactose. **Side-effects:** Headache, palpitations and tremor. Agitation, restlessness, sleep disturbances, muscle cramps, tachycardia, are uncommon. **Very rarely:** Exanthema, urticaria, pruritus, bronchospasm, hypokalaemia/hyperkalaemia. Nausea, taste disturbances, dizziness, angina, variations in the blood pressure and hyperglycaemia reported in isolated cases. Blood levels of insulin, free fatty acids, glycerol and ketone bodies may increase. **Precautions:** Advise patients to continue anti-inflammatory therapy with corticosteroids. Use regularly not as an alternative to short-acting β -agonists. Review therapy if symptoms persist, or treatment needs to be increased. The dose should not be initiated or increased during an exacerbation. Observe caution with concomitant sympathomimetics and in patients with thyrotoxicosis, phaeochromocytoma, cardiomyopathy, aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders. Additional blood glucose monitoring is recommended initially in diabetic patients. Potentially serious

hypokalaemia may result from β_2 -agonist therapy. Particular caution recommended in acute severe asthma as this effect may be potentiated by xanthine-derivatives, steroids, diuretics and hypoxia. Monitor serum potassium levels. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. Experience with Oxis Turbohaler in pregnancy is limited: only use after special consideration. Should not be given to breast feeding mothers. **Interactions:** Concomitant anti-arrhythmics, phenothiazines, antihistamines (terfenadine). MAOIs and tricyclic anti-depressants can prolong the QTc-interval and increase risk of ventricular arrhythmias. L-Dopa, thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant MAOIs, furazolidone and procarbazine may precipitate hypertension. Risk of arrhythmias in patients receiving anaesthesia with halogenated hydrocarbons. Do not give together with beta-blockers (including eye drops) unless essential. **Pharmaceutical precautions:** Store below 30°C. **Legal category:** POM **Package quantities:** Each inhaler provides 60 actuations. **Marketing Authorisation nos:** 0017/0386-7. For further information contact the **Marketing Authorisation Holder:** Astra Pharmaceuticals Ltd., Home Park, Kings Langley, Herts, WD4 8DH. Tel: (01923) 266191. Date of preparation: April 1998. © Oxis and Turbohaler are registered trademarks of Astra Pharmaceuticals Limited.

For further information, contact the Marketing Authorisation Holder: Astra Pharmaceuticals Limited, Home Park, Kings Langley, Herts WD4 8DH. Astra code number: OXIS98 3152.



ASTRA

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