IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0436/033/001
Case No: 2055550

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Norton Waterford Limited

T/A IVAX Pharmaceuticals Ireland, **Unit 301**, **IDA Industrial Park**, **Waterford**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Airomir Inhaler 100 micrograms per metered dose pressurised inhalation suspension

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **01/10/2008** until **18/09/2010**.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Airomir Inhaler 100 micrograms per metered dose pressurised inhalation suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 100 micrograms Salbutamol (as sulphate).

For excipients see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension
A homogenous, creamy – white to grey suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Airomir Inhaler is indicated for the treatment of acute attacks or exacerbations of bronchial asthma and for the treatment of reversible airways obstruction. Airomir Inhaler may also be taken prophylactically before exertion to prevent exercise-induced asthma.

4.2 Posology and method of administration

For oral inhalation use.

ADULTS AND CHILDREN: For the relief of acute bronchospasm and for managing intermittent episodes of asthma, one inhalation, increasing to two inhalations if necessary.

For prevention of exercise-induced bronchospasm, one inhalation before exertion, increasing to two inhalations if necessary.

ELDERLY: No special dosage recommendations are made for elderly patients.

For all patients, the maximum recommended dose should not exceed eight inhalations in 24 hours. With repetitive dosing, inhalations should not usually be repeated more often than every 4 hours.

Method of Administration:
Inhalation use.

4.3 Contraindications

Hypersensitivity to salbutamol or any of the inactive ingredients in Airomir Inhaler.

4.4 Special warnings and precautions for use

Salbutamol causes peripheral vasodilation which may result in reflex tachycardia and increased cardiac output. Caution should be used in patients suffering from angina, severe tachycardia or thyrotoxicosis.

Cardiovascular effects may be seen with sympathomimetic drugs including salbutamol. There is some evidence from post-marketing data and published literature of rare occurences of myocardial ischaemia assicuated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, tachyarrythmia or severe heart failure) who are receiving salbutamol for respiratory disease, should be warned to seek medical advice if they experience chest paing or other sumptims of worsening heart disease. Attention should paid to assessment of symptoms such as dyspnoea and chest pain, as they maybe be of either respiratory or cardiac origin.

The patient should be advised to seek medical advice if the treatment ceases to be effective and/or their asthma seems to be worsening, and not to increase the dose without medical advice.

In common with other beta-adrenoceptor agonists, salbutamol can induce reversible metabolic changes such as increased blood glucose levels. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of keto acidosis has been reported. Concurrent administration of glucorticoids can exaggerate this effect.

4.5 Interaction with other medicinal products and other forms of interaction

Salbutamol and non-selective beta-blockers should not usually be prescribed together. Caution should be exercised in its use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents. The effects of this product may be altered by guanethidine, reserpine, methyldopa, tricyclic antidepressants and monoamine oxidase inhibitors.

Because Airomir contains ethanol there is a theoretical potential for interaction in patients taking disulfiram or metronidazole. The amount of ethanol in Airomir is small but it may be enough to precipitate a reaction in some sensitive patients.

4.6 Pregnancy and lactation

Airomir Inhaler
There is no experience of this product in pregnancy and lactation in humans. An inhalation reproductive study with Airomir Inhaler in rats did not exhibit any teratogenic effects.

Propellant 134a
Studies of propellant 134a administered to pregnant and lactating rats and rabbits have not revealed any special hazard.

Salbutamol
Salbutamol should only be used during pregnancy and lactation if considered essential by the physician.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Frequency estimate: very common = 10%, common = 1 % to < 10 %; uncommon = 0.1 % to < 1 %; rare = 0.01% to < 0.1%; very rare < 0.01%.

Immune system disorders: Hypersensitivity reactions (very rarely).

Metabolism and nutritional disorder: Potentially serious hypokalaemia, raised serum lactate/Lactic acidosis (rarely).

Psychiatric disorders: Hyperactivity in children (rarely).

Nervous system disorders: Headaches (rarely).

Very rare: Cardiac arrythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles)

Respiratory, thoracic and mediastinal disorders: Paradoxical bronchospasm.

Musculoskeletal and connective tissue disorders: Mild tremor (rarely).

Unknown*: Myocardial ischaemia

* Reported spontaneously in post-marketing data therefore frequency regarded as unknown.

4.9 Overdose

A cardioselective beta - blocking agent should be administered, but these should be used with caution in patients with a history of bronchospasm. Hyperglycaemia and agitation have also been reported following overdose with Salbutamol.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Salbutamol is a sympathomimetic agent which has a selective action on beta-2-adrenergic receptors in bronchial smooth muscle.

5.2 Pharmacokinetic properties

Onset of action is usually within 10 minutes of inhalation and lasts 4-6 hours in most patients.

5.3 Preclinical safety data

Propellant 134a
In animal studies propellant 134a has been shown to have no significant pharmacological effects other than at very high exposure concentrations, when narcosis and a relatively weak cardiac sensitising effect were found. The potency of the cardiac sensitisation was less than that of CFC-11 (trichlorofluoromethane).

In studies to detect toxicity, repeated high dose levels of propellant 134a indicated that safety margins based on systemic exposure would be of the order 2200, 1314 and 381 for mouse, rat and dog with respect to humans.

There are no reasons to consider propellant 134a as a potential mutagen, clastogen or carcinogen judged from in vitro and in vivo studies including long-term administration by inhalation in rodents.

Airomir Inhaler
Safety studies with Airomir in rat and dog showed few adverse effects. These occurred at high doses and were consistent with the known effects of salbutamol inhalation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oleic Acid
Ethanol
Norflurane

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate or freeze.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

6.5 Nature and contents of container

Airomir Inhaler: Supplied as a complete unit delivering 200 inhalations.
10 ml Aluminium based Pressurised container fitted with a 25 microlitre metered dose value and supplied with a plastic inhalation adaptor.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For patients requiring a spacer device the Aerochamber has been shown to be compatible with Airomir Inhaler.

As the canister is pressurised, no attempt should be made to puncture or dispose of it by burning.

7 MARKETING AUTHORISATION HOLDER

Norton Waterford Limited
Unit 301
Industrial Park
Waterford
Ireland

Trading as:

IVAX Pharmaceuticals Ireland

8 MARKETING AUTHORISATION NUMBER

PA 436/33/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 September 1995

Date of last renewal: 19 September 2005

10 DATE OF REVISION OF THE TEXT

November 2007