Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Airomir Autohaler 100 micrograms per metered dose, pressurised inhalation suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each actuation of Airomir Autohaler delivers Salbutamol Sulphate Ph. Eur. equivalent to Salbutamol 100 micrograms into the mouthpiece of the adapter.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension
Pressurised aluminium container fitted with a 25 microlitre valve and supplied with a plastic breath-actuated actuator.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Airomir Autohaler is indicated for the treatment of acute attacks or exacerbations of bronchial asthma and for the treatment of reversible airways obstruction. Airomir Autohaler 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.

4.3 Contraindications

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

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 occurrences of myocardial ischaemia associated with salbutamol. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving salbutamol should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may 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.

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

4.6 Pregnancy and lactation

Airomir Autohaler

There is no experience of this product in pregnancy and lactation in humans. An inhalation reproductive study with Airomir 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

Airomir Autohaler has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Mild tremor, headache and transient muscle cramps may rarely occur. Potentially serious hypokalaemia has been reported in patients taking beta-2-agonist therapy. Hypersensitivity reactions and hyperactivity in children have been reported rarely.

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

Unknown: Myocardial ischaemia * (see section 4.4)

As with other inhalation therapy, paradoxical bronchospasm may occur immediately after dosing. In this instance, Airomir Autohaler should be discontinued immediately and alternative therapy instituted if necessary.

No additional adverse effects have been seen with this product.

*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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: RO3 AC02
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 Autohaler
Safety studies with the product 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 (Propellant 134a)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 30ºC.
Do not refrigerate or freeze. This canister contains a pressurised liquid.

Do not expose to temperatures higher then 50ºC. Do not pierce the canister.

6.5 Nature and contents of container

Airomir Autohaler: Supplied as a complete unit delivering 200 inhalations through a breath-actuated actuator. 10ml Aluminium based pressurised container fitted with a 25 microlitre metered dose valve and supplied with a plastic Autohaler actuator.

6.6 Special precautions for disposal and other handling

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

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 436/33/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last authorisation: 8th March 2007

10 DATE OF REVISION OF THE TEXT

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