Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Salbutamol CFC-Free 100 micrograms, pressurised inhalation, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each actuation delivers Salbutamol Sulphate equivalent to Salbutamol 100 micrograms per metered (ex valve) dose.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation suspension

A homogenous creamy white to greyish white suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of adminstration

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. For patients requiring a spacer device the Aerochamber has been shown to be compatible with Salbutamol CFC-Free.

4.3 Contraindications

Hypersensitivity to salbutamol or any of the inactive ingredients in Salbutamol CFC-Free.

4.4 Special warnings and special 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.

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

4.6 Pregnancy and lactation

Salbutamol CFC-Free
There is no experience of this product in pregnancy and lactation in humans. An inhalation reproductive study with Salbutamol CFC-Free 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

Mild tremor, headache, palpitations, tachycardia 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.

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

No additional adverse effects have been seen with this product.

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: RO3A-C02

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oleic acid
Ethanol
Propellant 134a

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store Salbutamol CFC-Free above 25°C. Protect from frost and direct sunlight.
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

Salbutamol CFC-Free: Supplied as a pressurised aluminium canister closed with a metering valve containing 200 inhalations.

6.6 Instructions for use and handling

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

Clean your inhaler every week. This is very important because sometimes the small hole where the medicine comes out can become blocked and therefore the inhaler is unable to work properly. Refer to the PIL on details how to clean your inhaler.
If your inhaler is blocked, or little or no medicine may come out when you press down the metal canister, this may be for the following reasons:

- A dirty or clogged mouthpiece. Wash and dry the mouthpiece as described in the PIL.
- Your inhaler may be empty, check by shaking the canister.
- Your inhaler may be incorrectly put together.

7 MARKETING AUTHORISATION HOLDER

Norton Waterford
T/A IVAX Pharmaceuticals Ireland
IDA Industrial Park
Cork Road
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 436/37/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 July 1998
Date of last renewal: 27 July 2003

10 DATE OF REVISION OF THE TEXT

August 2005