Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Salbutamol HFA 100 micrograms per metered dose pressurised inhalation suspension.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains salbutamol sulphate equivalent to salbutamol 100 micrograms.

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

The suspension is delivered via a pressurised metered dose inhaler, consisting of an aluminium canister sealed with a metered dose valve, packed into a blue L-shaped actuator (see also Section 6.5 Nature and contents of container).

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Salbutamol HFA Inhaler is indicated in the management of bronchial asthma, for the relief of wheezing and shortness of breath used on an as required basis. Salbutamol HFA Inhaler may be used as necessary to relieve attacks of acute dyspnoea and may be used to prevent recognised allergen or exercise induced bronchospasm.

Salbutamol HFA Inhaler may also be used in the treatment of reversible airways obstruction associated with chronic bronchitis and emphysema.

4.2 Posology and method of administration

ADULTS: For the relief of wheezing, shortness of breath and attacks of acute dyspnoea in patients with asthma, or reversible airways obstruction associated with chronic bronchitis and emphysema, one or two inhalations may be administered as a single dose.

For prophylaxis of recognized allergen or exercise-induced asthma, two inhalations.

CHILDREN: For the relief of wheezing, shortness of breath and attacks of acute dyspnoea in children with asthma, one inhalation increasing to two if necessary may be administered as a single dose.

For prophylaxis of recognised allergen or exercise-induced asthma, one inhalation increasing to two 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 that every 4 hours.

Instructions for Use (see also PIL for pictograms)

1. Remove the dust cap from the mouthpiece of the actuator (plastic case) by holding it between the thumb and forefinger and squeezing gently whilst pulling them apart. Check that there are no objects in the mouthpiece and that it is clean.

2. Hold the inhaler upright with your thumb on the base and your first finger on the top of the can, and shake well.

3. Breathe out slowly through your mouth as far as is comfortable and then immediately place the mouthpiece of the actuator fully into your mouth and close your lips lightly around it, but don't bite it.

4. Breathe in slowly and deeply and as you start to do so press the metal canister down firmly with your first finger to spray the aerosol and release the medicine. This action delivers a measured amount of Salbutamol HFA Inhaler.

5. Relax the pressure on the metal canister. Continue to breathe in steadily and deeply.

6. Remove the mouth piece of the actuator from your mouth while holding your breath for about 10 seconds, or as long as comfortable, then breathe out slowly.

7. If your doctor instructs you to take a further puff, wait for about one minute and then repeat steps 2 to 6.

8. Replace the dust cap on the mouthpiece by snapping it into place to protect the mouthpiece from dirt and dust.

Test Firing

Test the inhaler if it is new or has not been used for more than one week by shaking it well and firing two puffs into the air to check that it works.

If your Salbutamol HFA Inhaler gets very cold, remove the metal canister from the actuator and warm it by rolling between your hands. DO NOT USE ANY OTHER SOURCE OF HEAT TO WARM IT UP.

Cleaning

Clean the inhaler once a week. To clean it:

1. Remove the metal canister by gripping it firmly and pulling it out of the actuator. Then remove the dust cap from the actuator.

2. Clean the mouthpiece and dust cap in warm water. You can also add a mild detergent or baby bottle cleaning solution to the water, your pharmacist can advise you about this. If you use a cleaning solution rinse the actuator and dust cap in running water. DO NOT put the metal canister into water.

3. Dry the actuator and dust cap in a warm place, but avoid excessive direct heat.

Replace the dust cap and metal canister by reversing step 1.

Caution

The canister is pressurized – do not puncture or expose the canister to excessive heat even when empty.

4.3 Contraindications

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

Salbutamol HFA Inhaler is contraindicated for use in the management of premature labour and threatened abortion.

4.4 Special warnings and precautions for use

4.4.1 Special warnings

Potentially serious hyperkalaemia has been reported in patients taking beta-2-agonist therapy. Particular caution is advised in patients with severe asthma. Hypokalaemia may also occur in hypoxic patients and those treated with xanthine derivatives, steroids, diuretics and long-term laxatives. Extra care should therefore be taken if beta-2-agonists are used in these groups of patients and serum potassium should be monitored.

Unwanted stimulation of cardiac adrenergic receptors can occur in patients taking beta-2-agonist therapy.

Cardiovascular effects may be seen with sympathomimetic drugs, including salbutamol. There is some evidence from post-marketing data and published literature 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.

4.4.2 Special precautions for use

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.

Administer cautiously to patients with angina, severe tachycardia or thyrotoxicosis.

4.5 Interaction with other medicinal products and other forms of interaction

Salbutamol and beta-blockers should not usually be prescribed together.

Hypokalaemia occurring with beta-2-agonist therapy may be exacerbated by treatment with xanthines, steroids, diuretics and long-term laxatives.

Caution should be exercised in the use of salbutamol with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

The effects of salbutamol may be altered by guanethidine, reserpine, methyldopa, tricyclic antisepressants and monoamine oxidase inhibitors.

4.6 Fertility, pregnancy and lactation

Salbutamol HFA Inhaler should not be used in pregnancy and lactation unless the unexpected benefit to the mother is thought to outweigh any risk to the foetus or neonate.

The safe use of inhaled salbutamol during pregnancy has not been established but it has been in widespread use for many years in human beings without apparent ill consequence. In mice and rabbits large doses of salbutamol have been shown to be teratogenic.

It is not known whether salbutamol is distributed into breast milk.

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. Myocardial ischaemia has been reported spontaneously in post-marketing data therefore its frequency is regarded as unknown.

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 Inhalershould be discontinued immediately and alternative therapy instituted if necessary.

4.9 Overdose

Treatment:

Asthmatic patients: Monitor biochemical abnormalities, particularly hypokalaemia which should be treated with potassium replacement where necessary. Bete-adrenoreceptor antagonists, even beta-1-selective agonists, are potentially life-threatening and should be avoided.

Non-asthmatic patients: Monitor and correct biochemical abnormalities, particularly hypokalaemia. A non-selective beta-adrenoceptor antagonist (eg nadolol, propranolol) will competitively reverse both hypokalaemia and tachycardia (beta-1-selective drugs will be largely ineffective).

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

Salbutamol is readily absorbed from the gastro-intestinal tract, but the systemic absorption of the inhaled drug is low. The action of the inhaled salbutamol depends on direct stimulation of receptors in the lung. Onset of action is usually within 10 minutes of inhalation and lasts 4-6 hours in most patients.

Salbutamol is subject to first-pass metabolism in the liver: about half is excreted in the urine as an inactive sulphate conjugate. It does not appear to be metabolised in the lung and therefore its fate following inhalation therapy depends on the delivery method used, which determines the proportion of salbutamol inhaled relative to the proportion inadvertently swallowed. It has been suggested that the slightly extended half-life following inhalation may reflect slow removal of active drug from the lungs.

5.3 Preclinical safety data

Salbutamol has been in widespread use for many years: there have been no adverse clinical findings with Salbutamol HFA Inhaler which might reflect pre-clinical safety issues (see Pregnancy and Lactation).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Oleic Acid
Norflurane (HFA 134a)
Ethanol, Anhydrous

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years

6.4 Special precautions for storage

The canister contains a pressurised liquid.
Do not store above 25℃.
Do not pierce the canister.

6.5 Nature and contents of container

A pressurised metered dose inhaler consisting of:

- A blue welly-boot shaped plastic actuator with a removable dust cap at one end

and

- An aluminium container, with a silver ferrule valve.

Each complete unit contains 200 metered doses.

6.6 Special precautions for disposal and other handling

Patients should be advised fully on the technique for using their inhaler by referencing the full list of instructions provided in the Patient Information Leaflet. Instructions for use and cleaning are presented in Section 4.2: Posology and method of administration.

7 MARKETING AUTHORISATION HOLDER

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Grange Road,
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