PRINT
240 mm x 230 mm

SALBUTAMOL
HICAIRE

100 mcg/actuation
METERED DOSE INHALER
BRONCHODILATOR/
SELECTIVE BETA-2-ADRENORECEPTOR AGONIST

FORMULATION:
Each actuation delivers:
Salbutamol sulfate BP (equiv. to Salbutamol)……..…..100mcg
Propellant HFA 134a……..……..…….q.s.

INDICATIONS:
Salbutamol (Hicaire) is indicated in adults, adolescents and children aged 4 to 11 years. For babies and children under 4 years of age, see Dosage and Administration and Pharmacodynamic Properties.

Salbutamol (Hicaire) provides short-acting (4 to 6 hour) bronchodilation with fast onset (within 5 minutes) in reversible airways obstruction.

It is particularly suitable for the relief and prevention of asthma symptoms. It should be used to relieve symptoms when they occur, and to prevent them in those circumstances recognised by the patient to precipitate an asthma attack (e.g. before exercise or unavoidable allergen exposure).

Salbutamol (Hicaire) is particularly valuable as relief medication in mild, moderate or severe asthma, provided that reliance on it does not delay the introduction and use of regular inhaled corticosteroid therapy.

DOSAGE AND ADMINISTRATION:
Salbutamol (Hicaire) is for oral inhalation use only. Salbutamol (Hicaire) may be used with a spacer device by patients who find it difficult to synchronise aerosol actuation with inspiration of breath.

The aerosol spray is inhaled through the mouth into the lungs. After shaking the inhaler, the mouthpiece is placed in the mouth and the lips closed around it. The actuator is depressed to release a spray, which must coincide with inspiration of breath.

Adults (including the elderly):
For the relief of acute asthma symptoms including bronchospasm, one inhalation (100 micrograms) may be administered as a single minimum starting dose. This may be increased to two inhalations if necessary. To prevent allergen- or exercise-induced symptoms, two inhalations should be taken 10-15 minutes before challenge. For chronic therapy, two inhalations up to four times a day.

Paediatric Population
Relief of acute bronchospasm
The usual dosage for children under the age of 12 years: one inhalation (100 micrograms). The dose may be increased to two inhalations if required.
Children aged 12 years and over: Dose as per adult population.

Prevention of allergen or exercise-induced bronchospasm
The usual dosage for children under the age of 12 years: one inhalation (100 micrograms) before challenge or exertion. The dose may be increased to two inhalations if required.
Children aged 12 years and over: Dose as per adult population.

Chronic therapy
The usual dosage for children under the age of 12 years: up to two inhalations 4 times daily.
Children aged 12 years and over: Dose as per adult population.

A spacer device may be used to facilitate administration to children under 5 years of age.

On-demand use of Salbutamol (Hicaire) should not exceed 8 inhalations in any 24 hours. Reliance on such frequent supplementary use, or a sudden increase in dose, indicates poorly controlled or deteriorating asthma (see Special Warnings and Precautions).

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: Andrenergics, inhalants. Selective beta-2-andrenoreceptor agonists
ATC code: R03AC02
Salbutamol is a selective β_2-adrenoceptor agonist. At therapeutic doses it acts on the β_2-adrenoceptors of bronchial muscle providing short acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

Special Patient Populations
Children < 4 years of age
Paediatric clinical studies conducted at the recommended dose (SB020001, SB030001, SB030002), in patients < 4 years with bronchospasm associated with reversible obstructive airways disease, show that Salbutamol (Hicaire) has a safety profile comparable to that in children ≥ 4 years, adolescents and adults.

PHARMACOKINETIC PROPERTIES
Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulfate (phenolic sulfate) which is also excreted primarily in the urine. The faeces are a minor route of excretion.

After administration by the inhaled route between 10 and 20% of the dose reaches the lower airways. The remainder is retained in the delivery system or is deposited in the oropharynx from where it is swallowed. The fraction deposited in the airways is absorbed into the pulmonary tissues and circulation, but is not metabolised by the lung. On reaching the systemic circulation it becomes accessible to hepatic metabolism and is excreted, primarily in the urine, as unchanged drug and as the phenolic sulfate.

The swallowed portion of an inhaled dose is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. Both unchanged drug and conjugate are excreted primarily in the urine. Most of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

ADVERSE EFFECTS
The adverse effects caused by normally used inhaled doses of salbutamol are mild, typical for sympathomimetic agents, and they usually disappear with continued treatment.

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common, (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

Immune system disorders
Very rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse.
Metabolism and nutrition disorders
Rare: Hypokalaemia.
Potentially serious hypokalaemia may result from beta2 agonist therapy.
Nervous system disorders
Common: Tremor, headache.
Very rare: Hyperactivity.
Cardiac disorders
Common: Tachycardia.
Uncommon: Palpitations.
Very rare: Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles).
Unknown: Myocardial ischaemia* (see Special warnings and precautions for use)
Vascular disorders
Rare: Peripheral vasodilatation.
Respiratory, thoracic and mediastinal disorders
Very rare: Paradoxical bronchospasm.
Gastrointestinal disorders
Uncommon: Mouth and throat irritation.
Musculoskeletal and connective tissue disorders
Uncommon: Muscle cramps.
* reported spontaneously in post-marketing data therefore frequency regarded as unknown

CONTRAINDICATIONS:
Hypersensitivity to the active substance or any of the excipients.

Non-i.v. formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion.

SPECIAL WARNINGS AND PRECAUTIONS:
Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of drug to the lungs. Patients should be warned that they may experience a different taste upon inhalation compared to their previous inhaler.

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment, including lung-function testing, as patients are at risk of severe attacks and even death. Physicians should consider using the maximum recommended dose of inhaled corticosteroid and/or oral corticosteroid therapy in these patients.

The dosage or frequency of administration should only be increased on medical advice. If a previously effective dose of inhaled salbutamol fails to give relief lasting at least three hours, the patient should be advised to seek medical advice.

Increasing use of bronchodilators, in particular short-acting inhaled β_2-agonists, to relieve symptoms, indicates deterioration of asthma control. The patient should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective, or more inhalations than usual are required. In this situation the patient should be assessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid).

Severe exacerbations of asthma must be treated in the normal way.

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.

Salbutamol should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from β_2-agonist therapy, mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics. Serum potassium levels should be monitored in such situations.

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with an alternative presentation or a different fast-acting inhaled bronchodilator.

Salbutamol (Hicaire) should be discontinued immediately, the patient assessed, and if necessary, a different fast-acting bronchodilator instituted for on-going use.

INTERACTIONS:
Salbutamol and non-selective β-blocking drugs such as propranolol, should not usually be prescribed together.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy
Safety in pregnant women has not been established. No controlled clinical trials with salbutamol have been conducted in pregnant women. Rare reports of various congenital anomalies following intrauterine exposure to salbutamol (including cleft palate, limb defects and cardiac disorders) have been received. Some of the mothers were taking multiple medications during their pregnancies. Salbutamol (Hicaire) should not be used during pregnancy unless clearly necessary.

Breast-feeding
As salbutamol is probably secreted in breast milk, its use in nursing mothers requires careful consideration. It is not known whether salbutamol has a harmful effect on the neonate, and so its use should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.

Fertility
There is no information on the effects of salbutamol on human fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
None reported.

OVERDOSE
The most common signs and symptoms of overdose with salbutamol are transient beta agonist pharmacologically mediated events, including tachycardia, tremor, hyperactivity and metabolic effects including hypokalaemia (see Special Warnings and Precautions and Adverse Effects).

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored. Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without a prescription.

STORAGE CONDITIONS:
Store at temperatures not exceeding 30°C. Do not freeze. Protect from frost and direct sunlight.

As with most inhaled medications in aerosol canisters, the therapeutic effect of this medication may decrease when the canister is cold.

The canister should not be broken, punctured or burnt, even when apparently empty.
Replace the mouthpiece cover firmly and snap it into position.

AVAILABILITY:
19 mL aluminum aerosol container fitted with 50 miu signL metered valve and a plastic oral actuator x 200 metered actuations (box of 1's)

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