SALBUTAMOL

ASMACAIRE

2 mg / 5 mL Syrup

SELECTIVE BETA-2-ADRENORECEPTOR AGONIST

FORMULATION
Each 5 mL (1 teaspoonful) of syrup contains:
Salbutamol (as sulfate) . . . . . 2 mg

PRODUCT DESCRIPTION
Salbutamol (Asmacaire) 2 mg / 5 mL Syrup: Clear, colorless, odorless solution.

PHARMACODYNAMICS
Salbutamol is a selective beta-2 adrenoceptor agonist. At therapeutic doses it acts on the beta-2 adrenoceptors of bronchial muscle providing short acting (4-6 hours) bronchodilation in reversible airways obstruction.

PHARMACOKINETICS
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. The majority 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%. After oral administration, salbutamol 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. The bioavailability of orally administered salbutamol is about 50%.

Preclinical Safety Data
In common with other potent selective β2-agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of fetuses were found to have cleft palate at 2.5 mg/kg dose, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50 mg/kg/day orally throughout pregnancy resulted in no significant fetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. Reproductive studies in the rabbit at doses of 50 mg/kg/day orally (i.e. much higher than the normal human dose) have shown fetuses with treatment related changes; these included open eyelids (ablepharia), secondary palate clefts (palatoschisis), changes in ossification of the frontal bones of the cranium (cranioschisis) and limb flexure. In an oral fertility and general reproductive performance study in rats at doses of 2 and 50 mg/kg/day, with the exception of a reduction in number of weanlings surviving to day 21 post partum at 50 mg/kg/day, there were no adverse effects on fertility, embryofetal development, litter size, birth weight or growth rate.

INDICATIONS
Salbutamol is a bronchodilator indicated for the prevention and symptomatic relief of bronchospasm in patients with reversible obstructive respiratory diseases such as bronchial asthma. It may also be used to arrest premature labor in conjunction with parenteral salbutamol.

DOSAGE AND ADMINISTRATION
Syrup

Adults:	2 to 4 mg (5 – 10 mL) 3 to 4 times daily with a total dose of up to 32 mg (80 mL)
Elderly:	2 mg (5 mL) 3 to 4 times daily to be cautiously adjusted to 8 mg per dose (20 mL) if necessary
Children:	3 to 4 times daily
	2 – 6 years: 1 – 2 mg (2.5 – 5 mL) given 3 to 4 times daily
	6 – 12 years: 2 mg (5 mL) given 3 to 4 times daily
Over 12 years:	2 – 4 mg (5 – 10 mL) to be cautiously increased to a total dose not to exceed 24mg (60 mL) per day

CONTRAINDICATION
Salbutamol Sulfate is contraindicated in patients with history of sensitivity to Salbutamol. It should not be used in pregnant women because Salbutamol has been found to be teratogenic in mice and rabbits in large doses.

SPECIAL WARNINGS AND PRECAUTION
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 oral corticosteroid therapy and/or the maximum recommended dose of inhaled corticosteroid in those patients.
Patients should seek medical advice if treatment with Salbutamol syrup becomes less effective.
The dosage or frequency of administration should only be increased on medical advice.
Patients taking Salbutamol syrup may also be receiving short-acting inhaled bronchodilators to relieve symptoms.
Increasing use of bronchodilators in particular short-acting inhaled beta2-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 they need more inhalations than usual.
In this situation patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (eg. Higher doses of inhaled corticosteroids or a course of oral corticosteroid). Severe exacerbations of asthma must be treated in the normal way.
Patients should be warned that if either the usual relief with Salbutamol oral preparations is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.
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.

PREGNANCY AND LACTATION
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.
As with the majority of drugs, there is little published evidence of its safety in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the foetus at very high dose levels.

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.

DRUG INTERACTIONS
Salbutamol syrup and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.

OVERDOSE AND TREATMENT
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 Precautions and see Adverse Drug Reactions).
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.
Nausea, vomiting and hyperglycaemia have been reported, predominantly in children and when salbutamol overdose has been taken via the oral route.
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

ADVERSE DRUG REACTION
Salbutamol Sulfate may cause fine tremors of the skeletal muscle (particularly the hands), palpitations and muscle cramps. Large doses may cause slight tachycardia, tenseness and peripheral vasodilation. High doses administered parenterally have been associated with nausea, vomiting with adverse cardiac and metabolic effects.
Salbutamol Sulfate like beta$_2$-agonists may cause reversible hypokalemia and hyperglycemia, severity often dependent on the dose and route of administration. These effects are potentiated by concomitant therapy with corticosteroids, diuretics, xanthenes. Induced hypokalemia may provoke arrhythmias in patients receiving digoxin.

PRECAUTIONS
Salbutamol Sulfate should not be taken together with non-selective beta-blocking agents such as propranolol. Blood potassium level should be monitored when given to patients taking corticosteroids, diuretics, xanthines and patients under digoxin therapy. Administer with caution to patients suffering from thyrotoxicosis.

STORAGE CONDITION
Store at temperatures not exceeding 30ºC.

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

ADR REPORTING STATEMENT
For suspected adverse drug reaction, report to FDA: www.fda.gov.ph
Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

AVAILABILITY
Salbutamol (Asmacaire) 2 mg/5 mL Syrup: Boston round amber glass bottle x 60 mL (Box of 1's).

Market Authorization Holder
THE CATHAY YSS DISTRIBUTORS CO., INC.
2/F Vernida I Condominium, 120 Amorsolo St.
Legaspi Village Makati City

Manufacturer
E.L. LABORATORIES, INC.
109 North Main Avenue
Laguna Technopark, Biñan, Laguna

Registration No.: DRP-3880
Date of Authorization: April 10, 2012
Date of Revision of Package Insert: February 16, 2023