SALBUTAMOL

ASMACAIRE

℞

1 mg / mL
Solution for Inhalation
ANTIASTHMA

CYDC

FORMULATION
Each 2.5mL Solution for Inhalation contains:
Salbutamol Sulfate 3.0 mg equivalent to Salbutamol 2.5 mg

PRODUCT DESCRIPTION
Salbutamol (ASMACAIRE) 1 mg/mL Solution for Inhalation: Clear, colorless, odorless solution.

PHARMACODYNAMICS AND PHARMACOKINETICS
Salbutamol is a direct-acting sympathomimetic with predominantly beta-adrenergic activity and a selective action on $beta_2$ receptors (a $beta_2$agonist). This results in its bronchodilating action being more prominent than its cardiovascular effect.

Administration by inhalation results in the rapid onset (within 5 to 15 minutes) of bronchodilation which lasts for about 3 to 6 hours.

Salbutamol is readily absorbed from the gastrointestinal tract. It is subject to first-pass metabolism in the liver and possibly in the gut wall: the main metabolite is an inactive sulfate conjugate.

Salbutamol is rapidly excreted in the urine as metabolites and unchanged drug; there is some excretion in the faeces. It does not appear to be metabolized in the lung, therefore its ultimate metabolism and excretion following inhalation depends upon the delivery method used, which determines the proportion of inhaled salbutamol relative to the proportion inadvertently swallowed. It has been suggested that the majority of an inhaled dose is swallowed and absorbed from the gut.

The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours.

INDICATIONS
Salbutamol (ASMACAIRE) is indicated in the treatment of reversible airways obstruction, as in asthma and in some patients with chronic obstructive pulmonary disease.

DOSAGE AND ADMINISTRATION
For preventing or treating bronchospasm:

Per 2.5 mL of Solution for Inhalation contains 2.5 mg of Salbutamol

This medicine is used with a nebulizer and is taken by inhalation over five (5) to fifteen (15) minutes. Salbutamol (ASMACAIRE) Solution must not be injected.

- *Adults and children 12 years of age and older.* The usual dose is 50 drops (2.5 mL) to 100 drops (5 mL) 4 times daily.
- *Children up to 12 years of age:* The usual dose is 25 drops (1.25 mL) to 50 drops (2.5 mL) every 4 to 6 hours if needed.
- In adults, a maximum dose of 40 mg per day for the treatment of severe airways obstruction may be given under strict medical supervision in the hospital.

Dosage and frequency of administration should only be increased upon advice of the physician.

$Beta_2$ agonists are not appropriate for use alone in the treatment of more than mild asthma. Increasing need for, or decreased duration of effect of, inhaled salbutamol and other short-acting $beta_2$ agonists indicates deterioration of asthma control and the likely requirement for increased anti-inflammatory therapy.

CONTRAINDICATIONS
Salbutamol (ASMACAIRE) Solution for Inhalation is contraindicated in patients with a history of hypersensitivity to any of the components of the product.

$Beta_2$ agonists should not be used for threatened abortion. First trimester of pregnancy, eclampsia and severe pre-eclampsia, intra-uterine infection, intra-uterine fetal death, ante-partum hemorrhage, placenta praevia and cord compression.

WARNINGS AND PRECAUTIONS
Salbutamol (ASMACAIRE) Solution for Inhalation should be given with caution in hyperthyroidism, myocardial insufficiency, arrhythmias, susceptibility to QT-interval prolongation, hypertension and diabetes mellitus.

In severe asthma, particular caution is also required to avoid inducing hypokalemia as this effect may be potentiated by hypoxia or by concomitant administration of other anti-asthma drugs; plasma-potassium concentrations should be monitored.

Should patients with mild asthma find that more than one dose is required daily, then that should be a sign for additional treatment with anti-inflammatory drugs. Increasing need for, or decreased effect of, short-acting $beta_2$ agonists indicates deteriorating asthma and the requirement for stepping up therapy.

PREGNANCY AND LACTATION
There are no studies on birth defects in humans. Some studies in animals have shown that they cause birth defects when given in doses many times higher than the human dose.

The administration of any drug during pregnancy should only be considered if the expected benefit to the mother outweighs the potential risk to the fetus.

It is not known whether this drug is excreted in human milk. Although most drugs pass into the breast milk in small amounts, many of these drugs may be used safely while breast feeding.

DRUG INTERACTIONS
Concomitant administration of salbutamol and other $beta_2$ agonists corticosteroids, diuretics or xanthines increases the risk of hypokalemia and monitoring of potassium concentrations is recommended in severe asthma, where such combination therapy is the rule.

Beta-adrenergic blocking agents (e.g. acebutolol, atenolol, labetalol, metoprolol, nadolol, pindolol, propranolol, timolol) may prevent the adrenergic bronchodilators from working properly.

Disopyramide, quinidine, phenothiazines or procainamide may increase the risk of heart problems.

ADVERSE DRUG REACTIONS
Salbutamol and other beta agonists may cause fine tremor of skeletal muscle (particularly the hands), palpitations, tachycardia, nervous tension, headaches, peripheral vasodilation, and rarely muscle cramps.

Potentially serious hypokalemia has been reported after large doses. Hypersensitivity reactions have occurred including paradoxical bronchospasm, angioedema, urticaria, hypotension and collapse.

OVERDOSE AND TREATMENT
The expected symptoms with overdose are those of excessive beta-stimulation and/or occurrence or exaggeration of any of the symptoms listed under Adverse Effects.

Treatment consists of discontinuation of salbutamol together with appropriate symptomatic therapy.

There is insufficient evidence to determine if dialysis is beneficial for overdosage of salbutamol solution for inhalation.

STORAGE CONDITION
Store at temperatures not exceeding 30ºC.

AVAILABILITY
Salbutamol (Asmacaire) 1 mg/mL Solution for Inhalation: Amber Glass Bottle x 20 mL with eurodropper (Box of 1's)

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

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

Marketing Authorization Holder
THE CATHAY YSS DISTRIBUTORS CO., INC.
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Manufacturer
EL LABORATORIES, INC.
109 North Main Ave., Laguna Technopark, Biñan, Laguna

Reg. No.: DR-XY35555
Date of Authorization: July 21, 2009
Date of Revision of Package Insert: February 16, 2023

PI-ASM1-Inh-2

THE CATHAY YSS DISTRIBUTORS CO., INC.													PACKAGE DESIGN DEPARTMENT	PAGE 2 OF 2	
GENERIC NAME	SALBUTAMOL			PACK SIZE				Pantone Process Black C				SOFTWARE	CORELDRAW X7	DATE	Apr. 10, 2025
BRAND NAME	ASMACAIRE		DIMENSIONS(mm)	(H) 190 x (W) 105		COLORS						ITEM CODE	PI-ASM1-Inh-2		
DOSAGE STR	1 mg / mL	LAYOUT TYPE	Package Insert									DESIGN CODE	PI-ASM1-INH-0612-10		
DOSAGE FORM	Solution for Inhalation	REV NO.: 6	REASON	1) AO Compliance 2) Change pharmacological category to "Antiasthma: 3) Inclusion of Item Code 4) Inclusion of Rx symbol 5) Change revision date to Feb. 16, 2023 6) Change Item Code to PI-ASM1-Inh-2 7) spelling correction of hypokalemia & technopark.								FILE NAME	Asmacaire CYDC Insert.cdr		