SUMMARY OF PRODUCTS CHARACTERISTICS (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICALPRODUCT:

1.1 Brand Name : **Lebasma Syrup**

1.2 Generic Name : Salbutamol oral Solution BP

1.3 Strength : 2mg/5ml

1.4 Pharmaceutical Form : Oral Syrup

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each 5ml contains:

Salbutamol Sulphate	BP	
eq. to Salbutamol	BP	2 mg.
Flavoured base		q.s.
Colour: Carmoisine		

3. PHARMACEUTICAL FORM

Oral Syrup

Pink coloured, flavoured, palatable syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lebasma Syrup (Salbutamol) is indicated in the treatment of Asthma & other conditions associated with reversible airways obstruction, exacerbation of reversible airways obstruction (including nocturnal asthma), prophylaxis of allergen- or exercise induced bronchospasm.

4.2 Posology and method of administration

Asthma & other conditions associated with reversible airways obstruction:

Adult: 4 mg 3–4 times a day, maximum single dose 8 mg (but unlikely to provide much extra benefit or to be tolerated).

Elderly: Initially 2 mg 3–4 times a day, maximum single dose 8 mg (but unlikely to provide much extra benefit or to be tolerated).

Unlicensed Use: With oral use of Salbutamol is not licensed for use in children under 2 years.

4.3 Contraindications:

Lebasma Syrup should not be used in patients hypersensitive to any of the product ingredients. Salbutamol should not be used for threatened abortion during the first or second trimester of pregnancy. Salbutamol may show relaxation of uterine muscle. Therefore, use of salbutamol during labor for relief of bronchospasm should be restricted to those women in whom the benefits clearly outweigh the risk. Beta-receptor blocking drugs should be avoided during Salbutamol therapy because these drugs block the bronchodilator effect of Salbutamol.

4.4 Special warnings and special precautions for use:

Salbutamol should be used with caution in persons with cardiac arrhythmias, coronary insufficiency, convulsive disorders, and history of cardiac disease. β_2 agonist should be used with caution in hyperthyroidism, susceptibility to QT-interval prolongation and hypertension. Hypokalaemia: Potentially serious hypokalaemia may result from β_2 agonist therapy.

4.5 Interaction with other FPPs and Other forms of Interaction

Plasma concentration of Digoxin possibly reduced by Salbutamol, beta blocker drugs blocks the effects of Salbutamol, hypokalemia due to administration of loop or thiazide diuretics may be acutely worsened by Salbutamol. The effects of this product maybe altered by Guanethidine, Reserpine, Methyldopa, Tricyclic-antidepressants. The concomitantuse of Salbutamol and other oral sympathomimetic agents is not recommended since such combined use may lead to deleterious cardiovascular effects.

4.6 Pregnancy and lactation

Salbutamol should only be used in pregnancy and lactation if considered essential by the physician & if the expected benefits to the mother are greater than any potential risks to the foetus/neonate. As Salbutamol is probably secreted in breast milk its use in nursing mothers requires careful consideration.

Monitoring Requirements: In uncomplicated prematurelabour, it is important to monitor bloodpressure, pulse rate(should not exceed 120 beats per minute), ECG (discontinue treatment if signs ofmyocardial ischaemiadevelop), blood glucose and lactate concentrations, andthe patient's fluid andelectrolyte status (avoid over-hydration—discontinue drug immediately and initiatediuretic therapy ifpulmonary oedema occurs).

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The high dose of Salbutamol may show lactic acidosis & nausea. The most common side effect of Salbutamol is fine tremor of the hands, nervous tension, headache, muscle cramps, and palpitation. Side effects of β_2 agonist may include tachycardia, arrhythmias, peripheral vasodilation, myocardial ischaemia and disturbances of sleep and behaviour. Paradoxical bronchospasm (occasionally severe), urticaria, angiodema, hypotension collapse has also reported. High doses of β_2 agonist are associated with hypokalaemia.

4.9 Overdose

Symptoms: Hypokalemia may occur following overdose with Salbutamol.

Treatment: The preferred antidote is a cardio selective β-blocking agent used with caution in patients with a history of bronchospasm. Serum Potassium level should be monitored.

Potential for Drug Abuse and dependence: The potential of resistance does not seem to be high, but the widespread use of Salbutamol suggests that when applicable prophylactically, it should be carefully controlled.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: β_2-adrenorecepteragonist; bronchodilator

ATC Code: R03AC02

Mechanism of action:

Salbutamol stimulates β_2 adrenergic receptors which are Predominant receptors in bronchial smooth muscle of the lung. Stimulation of β_2 receptors leads to the activation of enzyme adenyl cyclase that form cAMP(adenosine mono-phosphate) from ATP(adenosine-tri phosphate). This high level of cAMP relaxes bronchial smooth muscle and decreases airway resistance by lowering intracellular ionic calcium concentrations. Salbutamol relaxes the smooth muscles of airways, from trachea to terminal bronchioles. High level of cAMP are also inhibiting the release of bronchoconstrictor mediators such as histamine, leukotreine from the mast cells in the airway.

5.2 Pharmacokinetic properties

After oral administration, Salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulphate. Both the unchanged drug and the conjugate are excreted primarily in the urine. The bioavailability of the orally administered Salbutamol is about 50%.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Excipient	Spec.
Sod. Methyl Hydroxybenzoate (Sod. Methylparaben)	BP
Sod. Propyl Hydroxybenzoate (Sod. Propylparaben)	BP
Liquid Sorbitol (Sorbitol Solution 70 %)	BP
Aspartame	BP
Acesulfame Potassium	BP
Menthol	BP
Xanthan Gum	BP
Essence Mixed Fruit Flavour (S1038)	IH
Colour Carmoisine	IH
Citric Acid Monohydrate	BP
Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30^0 C. Protect from light. Keep out of reach of children. Keep container tightly closed.

6.5 Nature and contents of container

100 ml in an amber coloured pet bottle in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

LEBEN LABORATORIES PVT. LTD.,

Business Address:

RO & Works : Plot No. L-4& L-15, Phase-III, MIDC, AKOLA–444 104 (MS), INDIA
Ph.:0091-724-2259401/02/03 & Fax:0091-724-2258371
E-mail- export@lebenlab.com, qad@lebenlab.com, ra@lebenlab.com

Mumbai Off. : 11, Mahavir Mansion, 70, Trinity Street, Near Metro Cinema,
MUMBAI–400 002 (MS), INDIA
Ph.: 0091-22-2207-5301, 02, Fax: 0091-22-2207-5303
E-mail – mumbai@lebenlab.com.

Country : INDIA

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