SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

1.1 Proprietary Name
LASTMOL TABLETS

1.2 Strength
Each tablet contains Salbutamol Sulphate BP equivalent to Salbutamol 4mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Quantitative Declaration
Each tablet contains Salbutamol Sulphate BP equivalent to Salbutamol 4 mg

For the full list of excipients see Section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Pink, circular, FFBE tablet scored on one side and plain on reverse, packed in PVC/Alu blister packs 10 x 10's in a unit box with literature insert.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications.
Salbutamol preparations is indicated in bronchial asthma of all types, chronic bronchitis and emphysema.

4.2 Posology and method of administration
Method of administration: Oral use.

Adults:

The usual effective dose is 2 - 4mg three or four times per day. If adequate bronchodilation is not obtained each single dose may be gradually increased to as much as 8mg. However, it has been established that some patients obtain adequate relief with 2mg three or four times daily. In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with 2mg three or four times per day.

Children:

The following doses should be administered three or four times daily.

2 - 6 years: 1-2 mg

6 - 12 years: 2 mg

Over 12 years: 2 – 4 mg. Some patients may require up to 8 mg.

Elderly patients should be given lower doses initially.

Children under 2 years of age: Product not recommended

The drug is well tolerated by children so that, if necessary, these doses may be cautiously increased.
"*The score line on the tablet is not intended for division of the tablet into two equal doses. The tablets should be swallowed whole."*

4.3 Contraindications

- Salbutamol should not be used for threatened abortion during the first or second trimester of pregnancy.
- Salbutamol and beta-blocking drugs such as propranolol should not usually be prescribed together.
- Salbutamol tablets are contraindicated in patients with a history of hypersensitivity to any of their components.

4.4 Special warnings and precautions for use.

Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose – galactose malabsorption should not take this medicine. Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Increasing use of bronchodilators in particular short-acting inhaled beta2-agonists to relieve symptoms indicates deterioration of asthma control. If patients find that short acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought.
Salbutamol causes peripheral vasodilation, which may result in reflex tachycardia and increased cardiac output.

Hyperthyroidism

Salbutamol should only be administered cautiously to patients suffering from thyrotoxicosis after careful evaluation of the benefits and risks of treatment. Constant monitoring of potassium levels in patients with severe asthma is essential, potentially serious hypokalaemia may result from beta-2 agonist therapy. In common with other β-adrenoceptor agonists, salbutamol can induce reversible metabolic changes such as increased blood glucose levels.

Diabetes
Administration of beta agonists is associated with a rise of blood glucose. Therefore, blood glucose and lactate levels should be monitored in diabetics and diabetic treatment adjusted accordingly to meet the needs of the diabetic during tocolysis. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of ketoacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect. 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 beta agonists.

Respiratory indications
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.

4.5 Interaction with other medicinal products and other forms of interaction
The effects of salbutamol may be altered by guanethidine, reserpine, methyldopa, tricyclic antidepressants and monoamine oxidase inhibitors. There is an increased risk of hypokalaemia if high doses of theophylline or high doses of corticosteroids are given with higher doses of salbutamol.

Halogenated anaesthetics
Owing to the additional antihypertensive effect, there is increased uterine inertia with risk of haemorrhage; in addition, serious ventricular rhythm disorders due to increased cardiac reactivity have been reported on interaction with halogenated anaesthetics. Treatment should be discontinued, whenever possible, at least 6 hours before any scheduled anaesthesia with halogenated anaesthetics.

Anti-diabetics
The administration of beta-agonists is associated with a rise of blood glucose, which can be interpreted as an attenuation of anti-diabetic therapy; therefore individual anti-diabetic therapy may need to be adjusted.

Potassium depleting agents

Owing to the hypokalaemic effect of beta-agonists, concurrent administration of serum potassium depleting agents known to exacerbate the risk of hypokalaemia, such as diuretics, digoxin, methyl xanthines and corticosteroids, should be administered cautiously after careful evaluation of the benefits and risks with special regard to the increased risk of cardiac arrhythmias arising because of hypokalaemia.

4.6 Pregnancy and Lactation

Salbutamol should only be used during pregnancy if it is considered essential by the physician.
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.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable Effect
The frequencies of adverse reactions are ranked according to the following MedDRA convention: Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

System organ	Common	Uncommon	Rar	Very rare	Not known
Immune system disorders				Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and	

Metabolism and nutrition disorders	Hypokalaemia (with high doses)	Hyperglycaemia			Lactic acidosis Metabolic
Nervous system disorders	Tremor Headache Dizziness			Hyperactivity	
Cardiac disorders	Cardiac arrhythmias* Tachycardia Palpitations	Myocardial ischemia		Peripheral vasodilation	
Respiratory, thoracic and mediastinal		Pulmonary oedema			
Gastrointestinal disorders	Nausea				Vomiting
Musculoskeletal and connective tissue disorders				Akathisia	Feeling of muscle tension.

* Including atrial fibrillation, supraventricular tachycardia and extrasystoles.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to **TMDA**

4.9 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.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists
ATC code: R03CC02.
Salbutamol is a selective beta-2-adrenergic agonist administered for the symptomatic relief bronchospasm associated with chronic or acute asthma, brochitis or other obstructive pulmonary diseases. Because of its relative specificity for β2receptors, salbutamol relaxes smooth muscle of the bronchi, uterus and vascular supply to the skeletal muscle, but generally has little or no action in therapeutic doses on cardiac muscles.

5.2 Pharmacokinetic Properties

Absorption

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%.

Elimination

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%.

5.3 Preclinical data safety

In common with other potent selective beta-2-agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate at 2.5mg/kg dose, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal 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 50mg/kg/day orally (i.e. much higher than the normal human dose) have shown foetuses 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Microcrystalline Cellulose pH 101.
- Dicalcium Phosphate.
- Sodium Lauryl Sulphate.
- White corn starch.
- Povidone K-30.
- Erythrosine Soluble Colour.
- Purified Water.
- Sodium Starch Glycolate.
- Purified Talc.

- Magnesium Stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in a cool dry place below 30°C.
Protect form light.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

Pink, circular, FFBE tablets scored on one side and plain on reverse, packed in PVC/Alu blister packs of 10 x 10's in a unit box along with literature insert.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6.7: Distribution Category

Prescription Only Medicine (POM).

7. MARKETING AUTHORIZATION HOLDER

Manufacturing Site Addresses Marketing Authorization Holder:
Company Name: LABORATORY & ALLIED LIMITED.
Address: Plot No. 209/10349, Opposite Sameer Business Park,
Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
Country: Kenya.
E-Mail: info@laballied.com.

Manufacturing Site Address:
Company Name: LABORATORY & ALLIED LIMITED.
Address: Plot No. 209/10349, Opposite Sameer Business Park,
Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
Country: Kenya.
E-Mail: info@laballied.com

8. MARKETING AUTHORIZATION NUMBER:

TAN 22 HM 0479

9. DATE OF FIRST REGISTRATION/ RENEWAL OF THE REGISTRATION:

05th December, 2022

10. DATE OF REVISION OF THE TEXT: