1.4 PRODUCT INFORMATION.
1.4.1 Prescribing information (Summary of Product Characteristics).
1. Name of the Finished Pharmaceutical Product.
Lastmol Tablets.

2. Qualitative and Quantitative composition.
Each tablet contains: Salbutamol Sulphate BP equivalent to Salbutamol 4mg
For the full list of excipients see Section 6.1.

3. Pharmaceutical form.
Tablets.
Pink, circular, FEBE tablet scored on one side and plain on reverse.

4. Clinical Particulars.
4.1 Therapeutic Indications.
Salbutamol sulphate is indicated in bronchial asthma of all types, chronic bronchitis and emphysema.

4.2 Posology and method of administration.
Route of administration: Oral.
Adults: 2mg to 4mg three to four times daily. Some patients may require upto 8mg.
Elderly patients should be given lower doses initially.
Children:
2 to 6 years: ½ to 1 one teaspoonful three to four times daily.
6 to 12 years: 1 teaspoonful three to four times daily or ½ tablet three to four times daily.

4.3 Contraindications.
Salbutamol is contraindicated in patients known to have hypersensitivity to any of their components.

4.4 Special Warnings and Precautions for Use.
Salbutamol should be used cautiously in patients with thyrotoxicosis. Salbutamol effects may be enhanced by concomitant use of aminophylline and other xanthines. Propranolol and other beta-adrenoreceptor drugs antagonize the action of Salbutamol and therefore should not be given with salbutamol. Salbutamol should be used with caution in hypersusceptible patients or those with hyperthyroidism, and in patients with diabetes mellitus, serious cardiovascular disorders or hypertension.

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 hypokalemic 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 as a result 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 Effects.
Salbutamol may cause fine tremors of skeletal muscles, particularly hand, palpitations and muscle cramps. Slight tachycardia, tenseness, headaches and peripheral vasodilations have been reported after large doses.

4.9 Overdose and treatment.
The preferred antidote for overdosage with salbutamol is a cardio selective beta blocking agent, but beta blocking drugs should be used with caution in patients with a history of bronchospasm. Hypokalemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

5. Pharmacological properties.
5.1 Pharmacodynamics properties.
Pharmacotherapeutic Group: Respiratory System, Drugs for Obstructive Airway Diseases, Adrenergics for Systemic Use, Selective beta-2-adrenoreceptor agonists.
ATC Code: R03CC02.
Pharmacological Properties: Salbutamol Sulphate is a selective bronchodilator and is sympathomimetic agent with predominant beta-adrenergic activity. It has a highly selective action on the receptors of bronchial muscles. It has little or no action in therapeutic doses on cardiac muscles.

5.2 Pharmacokinetic properties.
Salbutamol Sulphate is readily absorbed from the gastrointestinal tract and is subject to first pass metabolism in the liver. About half the dose is excreted in urine as an inactive sulphate conjugate. It has been reported that the half-life of oral Salbutamol Sulphate ranges from 2 to 7 hours.

5.3 Preclinical safety data.
No additional data of relevance other than the information provided in SPC.

6. Pharmaceutical Particulars.
6.1 List of Excipients.
- Dicalcium Phosphate
- Sodium Lauryl Sulphate
- Microcrystalline Cellulose pH 101
- White Corn Starch
- Povidone K-30
- Erythrosine Soluble Colour
- Purified Water
- Sodium Starch Glycolate
- Purified Talc
- Magnesium Stearate

6.2 Incompatibilities.
None.

6.3 Shelf Life.
36 months

6.4 Special Precautions for Storage.
Store in a dry place, below 30°C.
Protect from light.
Keep all medicines out of reach of children.

6.5 Nature and Contents of Container.
Packed in blisters of 10x10’s in a unit box and in 1000’s in HDPE container with literature insert.

6.6 Special precaution for disposal and other handling.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and 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

Telephone: +254 20 8040306
Telefax : +254 20 8040309
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
Telephone: +254 20 8040306
Telefax : +254 20 8040309
E-Mail : info@laballied.com

8. Marketing Authorization Number.
Kenya: H97/122.

9. Date of first Registration/ Renewal of the Registration.
Registration: 27/03/1997.
Renewal: To be retained annually.

10. Date of revision of the text:
August, 2023.