SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

SALBUTAMOL ORAL SOLUTION BP 2 MG / 5 ML (**SALBUREST**)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 ml contains:

Salbutamol Sulfate BP	
Eq. to Salbutamol	2 mg
Flavoured Syrup Base	Q.S.
Colour: Ponceau 4R	

List of Excipients with Notable Effect: Sucrose, Sodium Methyl Hydroxybenzoate, Sodium Propyl, Hydroxybenzoate, Ponceau 4R, Sodium Benzoate, Propylene Glycol, Aspartame

3. PHARMACEUTICAL FORM

Oral Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

Salbutamol is used as bronchodilators in the management of reversible airways obstruction, in prevention and relief of bronchospasm in all types of bronchial asthma and in some patients with chronic obstructive pulmonary disease.

4.2 Posology and Method of Administration

Adults: Minimum starting dose is 2 mg three times a day.
Usual effective dose is 4mg three or four times a day, which may be increased to a maximum of 8mg three or four times a day if adequate bronchodilation is not obtained.
Elderly: In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with the minimum starting dose.
Pediatric Population:
2 - 6 years: the minimum starting dose is 1mg three times daily. This may be increased to 2mg three or four times daily.
6 - 12 years: the minimum starting dose is 2mg three times daily. This may be increased to four times daily.
Over 12 years: the minimum starting dose is 2mg three times daily. This may be increased to 4mg three or four times daily.

4.3 Contraindications

Hypersensitivity to the salbutamol or any of the excipients.
Non-intravenous formulations of salbutamol must not be used to arrest uncomplicated premature labour or threatened abortion.

4.4 Special warnings and precautions for use

Salbutamol and other beta agonists 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 hypokalaemia as this effect may be potentiated by hypoxia or by the effect of other antiasthma drugs, plasma-potassium concentrations should be monitored.
Salbutamol is not appropriate for use alone in the treatment of more than mild asthma. Increasing need for, or decreased duration of effect of, salbutamol indicates deterioration of asthma control and the likely requirement for increased anti-inflammatory therapy.
Salbutamol can induce reversible metabolic changes such as increased blood glucose levels.

Patients with rare hereditary problems of Fructose Intolerance, Gluoose-Galactose malabsorption or Sucrase-lsomaltase insufficiency should not take this medicine.
Parabens may cause allergic reactions (possibly delayed).
Ponceau 4R May cause allergic reactions Sodium Benzoate may cause Irritations of the skin, mucous membranes and eyes (local application), risk of jaundice in newborns (injections)
Propylene Glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of Propylene Glycol to pregnant or lactating patients should be considered on a case by case basis.
Aspartame is Source of Phenylalanine. This medicine should be used with caution in patients with Phenylketonuria. Neither non-clinical nor clinical data are available to assess Aspartame use in infants below 12 weeks of age.

4.5 Interaction with other medicinal products and other forms of Interaction

Concurrent administration of salbutamol with corticosteroids, diuretics, or xanthines increases the risk of hypokalaemia, and monitoring of potassium concentrations is recommended in severe asthma.
Beta adrenergic blocking drugs inhibit the bronchodilator action of salbutamol and other sympathomimetic bronchodilators. However such drugs should not be used in asthmatic patients as they may increase airway resistance.
Care is recommended if it is proposed to administer salbutamol in concomitant therapy with other sympathomimetic amines as excess sympathetic stimulation may occur.

4.6 Pregnancy and lactation

Pregnancy: Salbutamol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Lactation: It is not known whether salbutamol is excreted in breast milk nor whether it has a harmful effect on the newborn. Thus, salbutamol should not be given to nursing mothers unless the benefits outweigh the risks.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Fine tremor (particularly in the hands), nervous tension, headache, muscle cramps, and palpitation. Other side effects include tachycardia, cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles), peripheral vasodilation, myocardial ischaemia, and disturbances of sleep and behaviour. Paradoxical bronchospasm (occasionally severe), urticaria, angioedema, hypotension, and collapse have also been reported. High doses of beta agonists are associated with hypokalaemia.

4.9 Overdose

Symptoms: The most common signs and symptoms of overdose with salbutamol are tachycardia, tremor, hyperactivity and metabolic effects including hypokalaemia. Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting beta-agonist therapy Nausea, vomiting and hyperglycaemia have been reported, predominantly in children.
Treatment: Consideration should be given to discontinuation of treatment and appropriate symptomatic treatment such as a cardio-selective beta-blocking agent given by intravenous injection, in patients presenting with cardiac symptoms (e.g. tachycardia, palpitations). Beta-blocking drugs should be used with caution as they may cause bronchospasm in sensitive individuals.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. Salbutamol is bound to plasma proteins to the extent of 10%. Both unchanged drug and conjugate are excreted primarily in the urine, a smaller proportion is excreted in the faeces. The plasma half-life of salbutamol has been estimated to range from 4 to 6 hours. The bioavailability of orally administered salbutamol is about 50%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipient(s)

Sucrose, Aspartame, Sodium Methyl Hydroxy Benzoate, Sodium Propyl Hydroxy benzoate, Citric Acid monohydrate, Sodium Citrate, Propylene Glycol, Sodium Benzoate, Menthol, Ponceau 4R, Raspberry Flavour No.1, Purified water.

6.2 Shelf-life

36 months

6.3 Special precautions for storage

Store below 30°C. Protect from light. Store in the original package.

6.4 Nature and contents of container

Pink Coloured Liquid With Raspberry Flavoured filled in 100 ml Amber color Round shape Pet Bottle 25 mm neck sealed with 25 mm ROPP Plain Golden cap. Such 1 Bottle is packed in a Printed Carton with 10 ml Measuring Cup Transparent 25 mm and Packing Insert.

7. MARKETING AUTHORISATION HOLDER

BIOMATRIX HEALTHCARE PVT LTD.
Survey No. 624, Sarkhej – Bavla Highway, Vil.: Rajoda,
Tal.: Bavla, Dist.: Ahmedabad – 382220, Gujarat, INDIA.