NKOYO SALBUTAMOL TABLETS 2 MG

1. NAME OF THE MEDICINAL PRODUCT

NKOYO SALBUTAMOL TABLETS 2 MG
Salbutamol Tablets BP 2 Mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative & Quantitative Formula

Sr. No.	Ingredients	Spec.	Unit Formula (mg)	Category
1	Salbutamol Sulphate BP Equivalent to Salbutamol	BP	2.400 Equivalent to 2.000	Active
2	Maize Starch	BP	77.100	Diluent
3	Dicalcium Phosphate	BP	8.000	Diluent
4	Color Erythrosine supra	IH	0.070	Coloring Agent
5	Lactose	IH	49.750	Diluent
6	Maize Starch	BP	7.280	Binding Agent
7	PVP-K-30	BP	1.000	Binding Agent
8	Sodium Benzoate	BP	0.050	Preservative
9	Purified water	BP	q. s.	Solvent
10	Purified Talc	BP	1.950	Lubricant
11	Maize Starch	BP	1.120	Lubricant
12	Magnesium Stearate	BP	1.280	Lubricant
	Weigh of Compressed Tablet		150.000	

3. PHARMACEUTICAL FORM

Oral Uncoated Tablet

Description: Pink ,flat faced beveled edge, round shaped uncoated tablets having embossing of “SALBUTAMOL” on one side and “MAX” break line “HEAL” on other side.

4. Clinical particulars

4.1 Therapeutic indications

Salbutamol Tablets are indicated in adults, adolescents and children aged 2 to 12 years.

1. For the relief of bronchospasm in bronchial asthmas of all types.
2. Chronic bronchitis.
3. Emphysema.

4.2 Posology and method ofadministration

Posology

Adults:

The usual effective dose is 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: 1-2mg

6-12 years: 2mg

Over 12 years: 2-4mg

The product is not recommended for children under 2 years of age. The drug is well tolerated by children so that, if necessary, these doses may be cautiously increased.

Method of administration

For oral use

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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.

4.4 Special warnings and precautions for use

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 $beta_2$-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 (see section 4.5). 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.

Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose – galactose malabsorption should not take this medicine.

Salbutamol tablets contain carmoisine (E122) which may cause allergic reactions

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 (see section 4.4).

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 as a result of hypokalaemia (see section 4.4).

4.6 Pregnancy and Lactation

Pregnancy

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

Breast-feeding

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

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).

organ class	Common	Uncommon	Rare	Very rare	Not known
Immune system disorders				Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse	
Metabolism and nutrition disorders					Lactic acidosis Hypokalaemia
Nervous system disorders					Headaches Myoclonus
Cardiac disorders					Peripheral vasodilation and compensatory increase in heart rate* Cardiac arrhythmias Myocardial ischemia**
Respiratory, thoracic and mediastinal disorders					Pulmonary oedema
Musculoskeletal and connective tissue disorders					Skeletal muscle tremor*** Tense feeling****

* With doses of salbutamol higher than those recommended or in patients who are unusually sensitive to beta-adrenergic stimulants.

** There have been spontaneously reports of myocardial ischemia in post-marketing experience (frequency unknown, see section 4.4).

*** A fine tremor, which occurs in some patients, usually the hands and the effects are dose related.

**** Due to the effects on skeletal muscle and not to direct CNS stimulation.

4.9 Overdose

The preferred antidote for over dosage 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.

Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists, ATC code: R03CC02

Salbutamol is a selective beta-2-adrenergic agonist administered for the symptomatic relief of bronchospasm associated with chronic or acute asthma, brochitis or other obstructive pulmonary diseases. Because of its relative specificity for β_2 receptors, salbutamol relaxes smooth muscle of the bronchi, uterus and vascular supply to the skeletal muscle, but generally has much less stimulant action on the heart than does isoproterenol which has powerful action on all beta receptors.

5.2 Pharmacokinetic properties

Absorption

Salbutamol is readily absorbed from the gastrointestinal tract. Its effects occur within 15 minutes and last for about 14 hours.

The peak plasma concentration of salbutamol and its metabolites is 5.1-11.7μg% at 2.5-3 hours after an oral dose of 4mg. Salbutamol does not cross the blood brain barrier to a significant extent, but it crosses the placental barrier.

Elimination

The drug is excreted in urine in about 24 hours, 50% of the drug being excreted within 4 hours.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients	Spec.
Maize Starch	BP
Dicalcium Phosphate	BP
Color Erythrosine supra	IH
Lactose	IH
Maize Starch	BP
PVP-K-30	BP
Sodium Benzoate	BP
Purified water	BP
Purified Talc	BP
Maize Starch	BP
Magnesium Stearate	BP

6.2 Incompatibilities

None known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Storage bellow 30°C, Protect from Light

6.5 Nature and contents of container

1000 tablets HDPE bottle pack

1000 tablets to be packed in HDPE bottle with a leaflet and silica gel bags.

1 Shipper contains: 60 container (60x1000) Tablets

6.6 Special precautions for disposal

No special requirements

7. APPLICANT/MANUFACTURER

NAFDAC REG.NO: 04-4295

MAXHEAL LABORATORIES PVT LTD

Plot No. - 2-7/80-85, Sursez, G.I.D.C

Sachin, Surat, Gujarat-394230.

India