Summary product characteristics:

1. Name of the medicinal product

Sabulin Syrup

2. Qualitative and quantitative composition

Each 5ml contains: Salbutamol (as Sulphate) 2mg.

For the full list of excipients, see section 6.1

3. Pharmaceutical form: Oral Syrup

Orange coloured, syrup, free from visible evidence of contamination.

4. Clinical particulars

4.1 Therapeutic indications

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

Salbutamol is a selective β2-agonist bronchodilator which provides short acting bronchodilator in reversible airways obstruction. Salbutamol is used to rapidly treat asthma, bronchospasm and reversible airways obstruction by widening the airways of the lungs. Salbutamol – Salbutamol Syrup 2mg/5ml is suitable for children and adults who are unable to use an inhaler device.

4.2 Posology and method of administration

Oral route of administration.

Posology:

Adults

The minimum starting dose is 2mg three times a day given as 5ml syrup. The usual effective dose is 4mg (10ml syrup) three or four times a day, which may be increased to a maximum of 8mg (20ml syrup) 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.

Paediatric Population

2 - 6 years: the minimum starting dose is 1mg as 2.5ml of syrup three times daily. This may be increased to 2mg as 5ml of syrup three or four times daily.

6 - 12 years: the minimum starting dose is 2mg as 5ml syrup three times daily. This may be increased to four times daily.

Over 12 years: the minimum starting dose is 2mg three times daily given as 5ml syrup. This may be increased to 4mg as 10ml syrup three or four times daily.

Salbutamol is well tolerated by children so that, if necessary, these doses may be cautiously increased to the maximum dose.

4.3 Contraindications.

Hypersensitivity to the active substance or any of the excipients in the formulation.

Although intravenous salbutamol and occasionally salbutamol syrup are used in the management of uncomplicated premature labour, salbutamol presentations should not be used for threatened abortion during the first or second trimester of pregnancy.

4.4 Special warnings and precautions for use.

Patients should be warned that if either the usual relief is diminished or the usual duration of action is reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Salbutamol causes peripheral vasodilation which may result in reflex tachycardia and increased cardiac output. Caution should be used in patients suffering from angina, severe tachycardia or thyrotoxicosis.

Caution should be exercised in its use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

Salbutamol should not cause difficulty in micturition (urination) because unlike sympathomimetic drugs such as ephedrine, it does not stimulate α-adrenoceptors. However, there have been reports of difficulty in micturition in patients with prostatic enlargement.

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

Use with caution in diabetic patients as this product may cause an increase in blood sugar levels. The development of ketoacidosis has been reported as diabetic patients may be unable to compensate for the increase in blood glucose. This effect can be exaggerated by concurrent administration of corticosteroids.

In patients with severe or unstable asthma, bronchodilators should not be the only or main treatment. With severe asthma regular medical assessment is necessary, including lung-function testing as patients are at risk of severe attacks or possibly death. For the treatment of such patients, physicians should consider using the max recommended dose of inhaled corticosteroids and/or oral corticosteroids.

β2-agonist therapy (from parenteral and nebulised administration) may result in potentially serious hypokalaemia. Special caution is required in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, diuretics and steroids. It is important to monitor serum potassium levels in such situations.

Patients taking Salbutamol may also be using short-acting inhaled bronchodilators to alleviate symptoms. A decrease in asthma control is indicated by an increase in the use of bronchodilators in particular short acting inhaled β-agonists. In such cases medical advice should be sought. Higher doses of inhaled corticosteroids or a course of oral corticosteroids may be considered.

Severe exacerbations of asthma must be treated in the usual manner.

4.5 Interaction with other medicinal products and other forms of interactions:

Caution should be exercised during use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents.

The effects of this product may be altered by guanethidine, reserpine, methyldopa, tricyclic antidepressants. Salbutamol oral preparations and beta-blocking drugs, such as propranolol should not usually be prescribed together.

4.6 Pregnancy and Lactation

Pregnancy: Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

As with the majority of drugs, there is little published evidence of its safety in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the foetus at very high dose levels.

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.

Effects on the ability to drive and use machines: None known.

4.7 Undesirable effects:

The most common side effect of Salbutamol is fine tremor of the hands, which may interfere with precise manual work. Tension, restlessness and a rapid heartbeat may also occur. There have been very rare reports of muscle cramps. Hypersensitivity reactions such as angiodema, urticaria, bronchospasm, hypotension and collapse have rarely been reported. Potentially serious hypokalaemia may result from β2-agonist therapy. Occasional headaches have also been reported. As with other drugs in this class rare reports of hyperactivity in children have been reported.

4.9 Overdose

The preferred antidote for overdose with salbutamol sulphate is a cardioselective beta-blocking agent, which should be used with caution in patients with a history of bronchospasm. Salbutamol overdose may lead to Hypokalemia (abnormally low potassium concentration in the blood). Serum potassium levels should therefore be monitored.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Selective beta-2-adrenoreceptor agonists

ATC code: R03CC02

Salbutamol is a selective beta-2 adrenoceptor agonist. As a beta-adrenergic stimulant for relief of bronchospasm such as it occurs with asthma, bronchitis, emphysema. It has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors.

5.2 Pharmacokinetic properties.

Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first pass metabolism in the liver. Peak plasma concentrations occur within one to four hours after oral administration. After multiple oral doses of salbutamol 4mg four times a day, steady-state plasma concentrations are obtained after 3 days. About half is excreted in the urine as an inactive sulphate conjugate following oral administration. The bioavailability of orally administered salbutamol is about 50%.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that in other sections of the SmPC

6. Pharmaceutical particulars

6.1 List of excipients

Natrosol 250 HHR
Bronopol
Flavour pineapple
Sodium saccharin
Sodium propyl paraben
Sodium methyl paraben
Sodium Benzoate
Citric acid
Colour sunset yellow
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years from the date of manufacture

6.4 Special precautions for storage

Store in a dry place, below 30^{0}C. Protect from direct sunlight. Keep out of reach of children

6.5 Nature and contents of container

60ml or 100ml amber coloured PET bottles in a unit carton with a literature insert included.

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

Dawa Limited,
Plot No.7879/8 Baba Dogo Road, Ruaraka
P.O Box 16633-00620 Nairobi –Kenya

8. Registration number(s)

Kenya registration number:H2006/633

9. Legal category: Prescription only medicine, **(POM)**

10. Date of revision of the text

September 2023.