For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Salmodil-SF Expectorant Syrup

(Salbutamol + Bromhexine Expectorant Syrup)

Description and Composition
Clear, pink colored solution having sweet and slightly bitter taste with cooling effect. 100 ml syrup filled in amber colored labeled PET bottle packed in a carton.
Each 5 ml contains: 2.41 mg Salbutamol Sulphate equivalent to Salbutamol 2 mg and 4.0 mg Bromhexine Hydrochloride.

Pharmacodynamics
Salbutamol is a synthetic sympathomimetic amine. Salbutamol stimulates beta-adrenergic receptors and has little or no effect on alpha adrenergic receptors. Beta-adrenergic agonists stimulate the production of cyclic adenosine- 3`,5`-monophosphate(AMP) by activation of the enzyme adenyl cyclase. Cyclic AMP appears to have greater stimulating effect on beta receptors of the bronchial, uterine, and vascular smooth muscles (beta-1 receptors).

Bromhexine is a mucolytic agent used in the treatment of respiratory disorders associated with viscid or excessive mucus.

Pharmacokinetics
Salbutamol sulfate is rapidly and well absorbed following oral administration.
Peak plasma salbutamol concentrations occur within 2.5 and 2 hours following administration of the conventional tablets and oral solution, respectively. Following oral administration of 2 mg of salbutamol every 6 hours as conventional tablets in healthy individuals, steady-state peak plasma salbutamol concentrations average 5.3-6.8 and steady-state through plasma Concentrations minutes 3.8-4.3 ng/mL. Bronchodilation begins within 30 minutes after oral administration of conventional tablets, with peak effect in 2-3 hours, and may persist up to 4-6 hours.

Results of animal studies indicate that salbutamol does not cross the blood-brain barrier, but the drug apparently crosses the placenta. After oral administration, the plasma half-life is reportedly 2.7-5 hours.

Following oral administration of salbutamol sulfate to healthy individuals, about 75% of a single dose is excreted in urine within 72 hours, mainly as the major metabolite; about 4% of the dose is excreted in feces. Bromhexine hydrochloride is rapidly absorbed from the gastro-intestinal tract and about 85 to 90% of a dose is excreted in the urine mainly as metabolites of bromhexine . Bromhexine is highly bound to plasma proteins.

Indications
A bronchodilator with mucolytic expectorant for cleareance of viscid purulent Sputum in acute and chronic brochiectasis and whooping cough.

Recommended dose for adult
Adults: 5ml 3 to 4 times a day
Children below 6 years: 1.25 to 2.5 ml 3 to 4 times a day.
Older children: 2.5 to 5ml 3 to 4 times a day.
Or as directed by the physician.

Mode of Administration
Oral

Contraindication
Thyrotoxicosis, angina pectoris, severe cardiovascular diseases and peptic ulcers.

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

Salbutamol oral preparations and non-selective beta-blocking drugs such as Propranolol, should not usually be prescribed together.

Salbutamol should be administered cautiously to patients suffering from thyroxicosis.

Potentially serious hypokalaemia may result from beta-2 agonist therapy.
Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia.

Since mucolytics may disrupt the gastric mucosal barrier, bromhexine should be used with care in patients history of peptic ulceration.

WARNING FOR ASPARTAME
Unsuitable for phenyl Ketonurics

Tocolysis: Serious adverse reactions including death have been reported after administration of terbutaline/salbutamol to women in labor. In the mother, these include increased heart rate, transient hyperglycaemia, hypokalaemia, cardiac arrhythmias, pulmonary oedema and myocardial ischaemia. Increased fetal heart rate and neonatal hypoglycaemia may occur as a result of maternal administration.

Very rare cases of chronically associated severe skin impairments such as Stevens Johnson Syndrome, Toxic Epidermal Necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP) have been reported. In most cases, these could be explained by the severity of the underlying disease or concomitant administration of another drug. In the early stages of such severe skin reactions, initially only nonspecific flu-like symptoms appear, e.g. fever, arthralgia, runny nose, cough, and sore throat. If skin or mucous membrane damage occurs, seek medical advice immediately and discontinue treatment as a precaution.

Interactions with Other Medicaments
Beta-blockers inhibit the bronchodilator effect of sympathomimetic bronchodilators. Diuretics and xanthines may augment hypokalemia. Hypokalemia associated with high doses of salbutamol may result in increased susceptibility to digitalis induced cardiac arrhythmiac.

Pregnancy and Lactation
Administration of salbutamol during pregnancy should only be considered if the expected benefit to mother is greater than any possible risk to fetus.

As salbutamol is probably secreted in breast milk, its use in nursing mothers is not recommended unless the expected benefits out weigh any potential risk.

Side Effects
Tachycardia, palpitation, precordial pain, nervousness, tremors in a few patients. Upper gastrointestinal complaints like nausea, vomiting may be observed in a few cases.

Immune System Disorders
Frequency not known: Anaphylactic reactions including anaphylactic shock.

Skin and Subcutaneous Skin Disorders
Frequency not known: Severe skin reactions (including Stevens Johnson syndrome, Toxic epidermal necrolysis (TEN), Erythema Multiforme (EM) and Acute Generalized Exanthematous Pustulosis (AGEP).

Symptoms and Treatment of Overdose
Salbutamol : The preferred antidote for overdosage with salbutamol is a cardioselective beta-blocking agent, but beta-blocking drugs should be used with caution in patients with a history of bronchospasm. Hypokalaemia may occur following overdosage with salbutamol. Serum potassium levels should be monitored.

Storage Condition
Store in a cool, dark and dry place below 30^{o}C

Shelf Life
24 months from the date of manufacture-finished product.

Presentation
100 ml syrup filled in amber colored PET round bottle with 25 mm ROPP Cap, packed in a carton along with package insert.

MAL No.: MAL20132279AZ

Date of Preparation: September 2018

Manufactured in India by:
FDC Limited
Regd. Office: B-8, MIDC Industrial Area,
Waluj, Aurangabad - 431 136, Maharashtra.

Product Registration Holder:
Unimed Sdn. Bhd
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200, Kuala Lumpur, Malaysia

2000009069

FDC Limited	LEAFLET
Mini Pharma Code No.: Front: 970/Back: 971	
Size	110 mm x 144 mm - Artwork Same Size
FoldedSize	UnfoldedSize
No. of Folds	
GSM	60 gsm
Paper	Maplitho Paper
Specifican No.	
Colour	■ PANTONE Process Black C
Artwork Code : 2000009069	Supercedes A/W Code: W1SJLL01AESMY
Location : Waluj - Country : Malaysia	Prepared On : 28-09-2018
HISTORY: 1) Under Warning & Precaution New Text Added (Which Received From party) 2) Immune System Disorders Added	