1.3.1
Summary Of Product Characteristics (SPC)

10.3.1 Product information for health professionals

1.3.1.1 Invented Name of the Medicinal Product

NECTALLIN

Bromhexine Hydrochloride, Salbutamol Sulfate, Guaifenesin & Methanol Syrup

1.3.1.2 Strength

Each 5 ml contains:

Bromhexine Hydrochloride BP……..2 mg

Salbutamol Sulfate BP

eq. to Salbutamol…….1 mg

Guaifenesin BP……50 mg

Menthol BP……..0.5 mg

Flavoured syrup base…….Q.S

Colour: Sunset Yellow

1.3.1.3 Dosage Form

Oral Dosage Form (Syrup)

1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Bromhexine Hydrochloride BP……..2 mg

Salbutamol Sulfate BP

eq. to Salbutamol…….1 mg

Guaifenesin BP……50 mg

Menthol BP……..0.5 mg

Flavoured syrup base…….Q.S

Colour: Sunset Yellow

1.3.1.5 PHARMACEUTICAL FORM

Oral Syrup

Orange coloured, clear syrupy liquid having Pineapple flavour.

1.3.1.6 CLINICAL PARTICULARS

1.3.1.6.1Therapeutic indications

NECTALLIN is indicated for clinical relief of cough associated with bronchitis, bronchial asthma, emphysema and other bronchopulmonary disorders where bronchospasm, mucous plugging and problems of expectoration co-exist.

1.3.1.6.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults:10- 20ml thrice daily (10ml)

Children: 6-12 yrs – 10ml thrice

Children: (under 6 yrs) -5-10 ml thrice daily

1.3.1.6.3 CONTRAINDICATIONS

Hypersensitivity to the components of the formulation.

1.3.1.6.4 WARNING AND PRECAUTIONS

While treating cough as a symptom, it is important to make every effort to determine and treat appropriately the underlying cause, such as specific infection. Caution should be observed while prescribing NECTALLIN to patients with hypertension, cardiovascular disease (including arrhythmias, coronary insufficiency, uncontrolled diabetes mellitus & patients with hyperthyroidism, history of seizures or in patients who are unusually responsive to sympathomimetic amines.

Patients susceptible to hypokalemia should be monitored because transient early falls in serum potassium have been reported with beta agonists. Since, mucolytics, such as bromhexine may disrupt the gastric mucosal barriers, bromhexine should be used with care in patients with a history of peptic ulceration.

1.3.1.6.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER

FORMS OF INTERACTION

Sympathomimetic agents: Concomitant use of NECTALLIN with other oral sympathomimetic agents is not recommended.

Beta-receptor blocking agents and Salbutamol inhibit the effect of each other.

Monoamine oxidase inhibitors: Salbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants since the action of Salbutamol on the vascular system may be potentiated.

Others

Eascof Expectorant should be used with caution in patients with diabetes mellitus, serious cardiovascular disorders, hypertension, hyperthyroidism and peptic ulcers.

1.3.1.6.6 PREGNANCY AND LACTATION

Pregnancy

This combination is not recommended for use in pregnancy.

Lactation

It is not known whether this combination is secreted in breast milk

Pediatric Use

Safety and effectiveness in children under the age of two years has not yet been adequately demonstrated.

1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None stated.

1.3.1.6.8 UNDESIRABLE EFFECTS

These are generally mild and very rare. However, In isolated cases, fine finger tremors, palpitation gastrointestinal disturbances, fatigue, dry mouth and dysuria may be seen.

1.3.1.6.9 OVERDOSE

None stated

1.3.1.7 PHARMACOLOGICAL PROPERTIES

Salbutamol is a beta-adrenergic stimulant which has a highly selective action on the β2 -receptors in bronchial muscle resulting in 2 bronchodilations, and in therapeutic doses, little or no action on thevβ1cardiac receptors.

Bromhexine is a derivative of the alkaloid vasicine and possesses mucokinetic (improvement in mucus transport) and mucolytic properties. It depolymerises mucopolysaccharides directly as well as liberating lysosomal enzymes. It promotes the removal of tenacious secretions in the respiratory tract and reduces mucus stasis (arresting the secretion of mucus).

Guaifenesin, by increasing respiratory tract fluid, reduces the viscosity of tenacious secretions and acts as an expectorant. Another possible mechanism by which it acts is by increasing the water bonding in the sputum, thereby decreasing its viscosity and leading to an increase in mucokinesis. is effective in both productive and nonproductive coughs.

Menthol is having soothing action.

1.3.1.7.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

1.3.1.8. PHARMACEUTICAL PARTICULARS

1.3.1.8.1 List of excipients

Excipient	**Specification**
Sucrose	BP
Propylene Glycol	BP
Enisweet EP Powder	BP
Arrowcell CRT/ Arrow Gum Super	BP
Sodium Benzoate	BP
Citric Acid	BP
Colour Sunset Yellow	IHS

Pineapple M-452 Flavour	IHS
Methyl Paraben	BP
Propyl Paraben	BP
Raspberry RM-335 Flavour	IHS
Purified Water	BP

1.3.1.8.2 Incompatibilities:

Not applicable

1.3.1.8.3 Shelf life:

3 year

1.3.1.8.4 Special precautions for storage:

Store below 30°C.Protect from Light.

1.3.1.8.5 Nature and contents of container:

NECTALLIN is available 100 ml bottle in carton.

1.3.1.8.6 Special precautions for disposal and other Special handling:

No special requirements.

1.3.1.9 Marketed by:

NECTAR HEALTHCARE LTD.,
16B Residence road, Gbagada Estate phase II,
Gbagada, Lagos, Nigeria.

1.3.1.10 Manufactured by:

ENICAR PHARMACEUTICALS PVT. LTD.

J-214, 215, 216, M.I.D.C.,

Tarapur, Boisar,

Dist. Palghar – 401 506, India.