SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

PHINOL TABLETS

1.3Product Information

1.3.1 SPC, Labeling and Package Leaflet

SPC-Summary of Product Characteristics

1. Name of the Medicinal Product

PHINOL-F

2. Qualitative and Quantitative Composition

Each uncoated tablet contains

Salbutamol Sulphate BP	
Eq to Salbutamol	2 mg
Theophylline Anhydrous BP	120 mg
Excipients	q.s.

3. Pharmaceutical Form

Oral Tablets

4. Clinical Particulars

4.1 Therapeutic Indications

PHINOL-F is used for Asthma, Respiratory diseases, lung disorders, wheezing, shortness of breath, chest tightness, interruption of breathing in new borns

4.2 Posology and Method of Administration

Oral

Emphysema, Chronic Bronchitis, Asthma

Adults: 1 or 2 tablets, 3 to 4 times daily

Children under 6 years: Salbutamol (0.5 – 1 mg) + theophylline (25 – 50 mg) t.i.d or q.i.d.

4.3 Contraindications

Hypersensitivity to the active ingredient or to any of the excipients

PHINOL-F is contraindicated in the following conditions

Antepartum hemorrhage, Cardiac disease, eclampsia and severe pre-eclampsia intrauterine infection, intrauterine foetal death and Placenta praevia

4.4 Special Warnings and Precautions for use

Caution should be exercised in patients with hepatic impairment, cardiac failure, hypertention, arrhythmias, pulmonary oedema, hyperthyroidism, diabetes mellitus, history of peptic ulcers and convulsive disorders, patients on MAOIs or tricyclic antidepressants, high fever

Caution is recommended when treating neonates and infant and in pregnancy and lactation

4.5 Interactions with other medicinal products and other forms of interactions

Increased theophylline toxicity with propranolol, cimetidine, erythromycin, quinolone antibiotics. Reduced efficacy with rifampicin, phenobarbitone, phenytoin, carbamazepine, sulfinpyrazone and smoking. Increased risk of hypokalemia with diuretics

Potentially fatal: With anaesthetics, pancuronium bromide and sympathomimetics (increased risk of arrhythmias)

4.6 Fertility, Pregnancy and Lactation

PHINOL-F should be used in pregnancy and breast-feeding only when clearly necessary

4.7 Effects on ability to drive and use machines

None expected at recommended doses and duration of therapy.

4.8 Undesirable Effects

Seizures, tremors, muscle cramps, palpitations, hypokalemia, headache, anorexia, nausea, anxiety, irritability, insomnia, rarely rash and angioedema

Potentially fatal: Arrhythmias including premature ventricular contractions

4.9 Overdose

Give supportive measures and symptomatic treatment. Drug can be removed from the body by gastric lavage or by inducing emesis. Absorption of drug can be reduced by administration of activated charcoal.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Theophylline inhibits phosphodiesterase enzyme which degrades cyclic nucleotides intracellularly and it results the cyclic AMP accumulation in the cell. This causes bronchodilatation, cardiac stimulation and vasodilatation. This drug release calcium from sarcoplasmic reticulum, especially in cardiac muscles and results in increased cardiac muscle contraction. This drug also blocks adenosine receptors (adenosine acts as a local mediator in CNS & CVS and other organs- which

contracts smooth muscles, especially in bronchi, blood vessels etc). This results bronchodilatation and vasodilatation.

Salbutamol is a short acting receptor agonist. It selectively stimulates receptors present in airway, Uterus, and Vascular Smooth muscles. It directly relaxes the airway smooth muscles and produces bronchodilation. Stimulation of receptors activates Gs adenylyl-cyclase -cyclic AMP pathway and produces reduction in smooth muscle tone. This receptor agonists also increases the conductance of large Ca2+sensitive K+ channels in airway smooth muscles and leads to membrane hyperpolarisation and relaxation of smooth muscles. This receptor agonists also suppress the release of Leukotrienes and histamine from the mast cells in the lung tissue and enhance mucociliary function and decrease micro vascular permeability and also inhibits Phospholipase A2 which produces inhibition of prostaglandins production. Thus Salbutamol can inhibit the broncho-constriction produced by inflammatory mediators. Salbutamol is effective in the management of preterm labour.

5.1 Pharmacokinetics

Salbutamol is a selective β2-agonist. It causes bronchial smooth muscle relaxation via the cyclic adenyl cyclase (cAMP) system. Theophylline is a phosphodiesterase inhibitor. It enhances intracellular cAMP conc thereby contributing to bronchial smooth muscle relaxation. It also suppresses airway hyper-response to stimuli. Advantage of this combination is the additive effect allowing reduction of individual doses.

5.2 Pre Clinical Safety Data

No data of relevance, which is additional to that already, included in other sections of the SPC.

5. Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch
Di basic calcium phosphate
Titanium Dioxide
Sodium methyl Paraben
Sodium propyl Paraben
Maize Starch

Purified Water
Talcum
Magnesium Stearate

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months from the Date of Manufacture

6.4 Special precautions for Storage

Store below 30°C

6.4 Nature and contents of Container

50 tablets pack in an HDPE jar

6.5 Special precautions for disposal

6. Marketing Authorization Holder

7. Marketing Authorisation Numbers

8. Date of First Authorisation/Renewal of Authorisation

9. Date of Revision of the text

1.3.2 Labeling

Particulars on the outer packing

1. Name of the Medicinal Product

PHINOL-F

2. Statement of the Active Substance

Each uncoated tablet contains

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Excipients	q.s.

3. List of the Excipients

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Sodium methyl Paraben
Sodium propyl Paraben
Maize Starch
Purified Water
Talcum
Magnesium Stearate

4. Pharmaceutical form and Content

Oral Tablets

5. Method and Route of Administration

Oral Route

6. Special Warning

To be sold by retail on the prescription of a medical practitioner only.

7. Other Special Warnings

Not Applicable

8. Expiry Date

36 months from the Date of Manufacture

9. Storage Conditions

Store below 30°C

10. Precautions for disposal of unused Medicinal Product

If the product is not used within the Expiry Date kindly refer your pharmacist for proper disposal of unused medication.

11. Name and Address of the Marketing Authorisation Holder

12. Marketing Authorisation Number

Trioplus Pharmaceuticals Pvt Ltd

13. General Classification for Supply

To be sold against the Prescription of the Registered Medical Practitioner only.

14. Instructions on use

As advised by the physician

15. Information in Braille

PHINOL-F