SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

TRIMEX DIABETIC COUGH SYRUP

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Trimex Diabetic Cough Syrup

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Trimex Diabetic Cough Syrup

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Syrup

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4.1. Therapeutic indications

Trimex Diabetic Cough Syrup is a combination of three active ingredients whose pharmacological action varies as per content. Guaifenesin increases the volume and reduces the viscosity of tenacious sputum , chlorpheniramine is H1 antagonist and possess considerable anti-histaminic activity.it blocks the action of histamine that results in increased capillary permeability and formation of oedema and wheal which treats nasal allergies and reduces sneezing while pseudoephedrine is both a direct and indirect acting sympathomimetic agent on adrenergic receptors which relieves nasal congestion

4.2. Posology and method of administration

Route of administration: Oral

Dosage: Dosages are dependent on the parasite involved, the weight of the Patient

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients.
Chlorpheniramine; Acute asthma, hypersensitivity to any of the ingredients or other antihistamines. Premature infants or neonates because of their increased susceptibility to the ant muscarinic effects. This medicine should not be given to patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

4.5 Interaction with other medicinal products and other forms of interaction

If urine is collected within 24 hours of a dose of Trimex diabetic a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5- hydroxy indoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA)
Chlorpheniramine; This medicine may enhance the sedative effects of alcohol, hypnotics, anxiolytics, sedatives, opioid analgesics and neuroleptics.

Concomitant use of pseudoephedrine with tricyclic antidepressants, other sympathomimetic agents (such as decongestants, appetite suppressants and

amphetamine-like psychostimulants) or with monoamine oxidase inhibitors (including furazolidone), which interfere with the catabolism of sympathomimetic amines

4.6 Pregnancy and lactation

Insufficient information is available on the effects of administration of Guaifenesin during human pregnancy. Guaifenesin, like most medicines, should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus.

Guaifenesin is excreted in breast milk in small amounts with no effect expected on the infant

Chlorpheniramine; There are no adequate controlled studies of Chlorpheniramine in pregnant women and this medicine should therefore not be used during pregnancy.

4.7 Effects on ability to drive and use machines

Chlorpheniramine may cause blurred vision, dizziness, drowsiness and interfere with human performance and therefore may seriously influence the ability to drive and operate machinery.

4.8 Undesirable effects

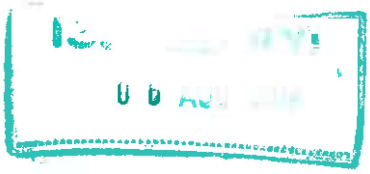
Side effects resulting from guaifenesin administration are very rare.

Chlorpheniramine; The product may cause drowsiness, which may progress to deep sleep, headache, dizziness, psychomotor impairment, inability to concentrate, lassitude, irritability and antimuscarinic effects such as urinary retention, dry mouth and blurred vision. Gastrointestinal disturbances may occur including abdominal pain, dyspepsia and anorexia. Paradoxical CNS stimulation may occur especially in children or after high doses. Skin rashes including exfoliative dermatitis and photosensitivity reactions and hypersensitivity reactions including urticaria may occur. Other side effects include convulsions, sweating, myalgia, paraesthesia, tinnitus, palpitations, tachycardia, arrhythmias, chest pain, haemolytic anaemia and other blood dyscrasias, extrapyramidal effects, tremor, liver dysfunction, including hepatitis and jaundice, sleep disturbances, including nightmares, depression, hypotension, hair loss, thickening of bronchial secretions and confusional psychosis in the elderly.

5. PHARMACOLOGICAL PROPERTIES

Mechanisms of Action/Effect

Guaifenesin is thought to exert its pharmacological action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and in reflex increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Other actions may include stimulating vagal nerve endings in bronchial secretory glands and stimulating certain centers in the brain which in turn



enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours

Chlorpheniramine antagonizes competitively the effects of histamine on H_1-receptors and also has weak antimuscarinic and moderate antiserotonin and local anaesthetic actions. It penetrates the brain and causes stimulation or sedation in animals.

Pseudoephedrine has direct and indirect sympathomimetic activity and is an effective upper respiratory decongestant. Pseudoephedrine is less potent than ephedrine in producing both tachycardia and elevation of systolic blood pressure and is less potent in causing stimulation of the central nervous system. Pseudoephedrine produces its decongestant effect within 30 minutes, persisting for at least 4 hours.

5.2 Pharmacokinetic properties

Absorption

Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information is available on its pharmacokinetics. After the administration of 600 mg guaifenesin to healthy adult volunteers, the Cmax was approximately 1.4 ug/ml, with tmax occurring approximately 15 minutes after drug administration.

Menthol is well absorbed from the gastrointestinal tract following oral administration.

Distribution

No information is available on the distribution of guaifenesin or menthol in humans.

Metabolism and elimination

Guaifenesin appears to undergo both oxidation and demethylation. Following an oral dose of guaifenesin to 3 healthy male volunteers, the t½ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours.

Menthol is hydroxylated in the liver by microsomal enzymes to p-methane -3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the glucuronide.

5.3 Preclinical safety data

The antihistaminic potency of Chlorpheniramine is confined mainly to its (+)-isomer. The racemate is similarly or slightly more toxic because of the contribution of (-)-isomer. The toxicity may therefore be non- specific, perhaps attributable to local anaesthetic action and the toxic effects (excitation/sedation, coma, convulsions and death) resemble those of other classic H_1antihistamines. Toxic doses may cause hypotension attributable to myocardial depression, an effect which is clearer with the (-)-isomer.

6. PHARMACEUTICAL PARTICULARS

6.1. List of ingredients

Guaifenesin

Chlorpheniramine Maleate

Pseudoephedrine HCl

Propylene Glycol
Alcohol 90%
(Rectified Spirit)
Sodium Saccharin (mesh 40-80)
Methyl Paraben
Propyl Paraben
Ponceau 4R Red 7 Colour (E124)
Hydroxyethyl Cellulose
(Natrosol HHX250)
Rasberry flavour

6.2. **Incompatibilities**

Not applicable.

6.3. **Shelf life**

36 months

6.4. **Special precautions for storage**

Store below 25^0 C, in a dry place. Protect from light keep out of reach of children.

Legal category:
Pharmacy Sale (P)

6.6Special precautions for disposal and other handling

No special requirements.

7. REGISTRANT

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