Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Trimex Paediatric Cough Expectorant

2. Qualitative and quantitative composition

Each 5mL contains:

Chlorpheniramine Maleate BP 1.0mg

Pseudoephedrine HCl 15.0mg

Guaifenesin BP 50.0mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Orange coloured, clear viscous syrup free from visible impurities.

4. Clinical particulars

4.1. Therapeutic indications

This product is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough, which are benefited by the combination of a decongestant of the mucous membranes of the upper respiratory tract, especially the nasal mucosa and sinuses, and an expectorant

4.2. Posology and method of administration

Posology

Adults and children aged 12 years and over:

Oral. 10 ml syrup every 4 - 6 hours up to 4 times a day. Maximum daily dose: 40 ml Children under 12 years: This product is contraindicated in children under the age of 12 years (see section 4.3).

The elderly: Normal adult dosage is appropriate, [See Pharmacokinetics in the elderly].

Hepatic dysfunction: Experience with the use of the product suggests normal adult dosage is appropriate, although it may be prudent to exercise caution in the presence of severe hepatic impairment, [See Pharmacokinetics in the elderly.

Renal dysfunction: Caution should be exercised when administering this product to patients with moderate to severe renal impairment, particularly if accompanied by cardiovascular disease, [See

Pharmacokinetics in Renal Impairment]. Do not exceed the stated dose. Keep out of the reach and sight of children.

Method of Administration

Oral

4.3. Contraindications

Not to be used in children under the age of 12 years.
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
This product is contraindicated in individuals with severe hypertension or severe coronary artery disease.
This product is contraindicated in individuals who are taking, or have taken, monoamine oxidase inhibitors within the preceding two weeks.
The concomitant use of pseudoephedrine and this type of product may occasionally cause a rise in blood pressure

4.4. Special warnings and precaution for use

Although pseudoephedrine has virtually no pressor effects in normotensive patients, this product should be used with caution in individuals suffering from mild to moderate hypertension, [See Contraindications and interactions with other medicinal products].

As with other sympathomimetic agents, this product should be used with caution in individuals with heart disease, diabetes, hyperthyroidism, elevated intra-ocular pressure or prostatic

enlargement.

This product should be not used for persistent or chronic cough, such as occurs with asthma, or emphysema where cough is accompanied by excessive secretions, unless directed by a physician.

Caution should be exercised when using the product in the presence of severe hepatic impairment or renal impairment (particularly if accompanied by cardiovascular disease), [See Pharmacokinetics].

Not more than 4 doses should be given in any 24 hours.

Do not exceed the stated dose.

Do not take with any other cough and cold medicine

4.5. Interactions with medicinal products and other forms of interaction

Concomitant use of this product with anti-hypertensive agents, tricyclic antidepressants, sympathomimetic agents (such as decongestants, appetite suppressants and amfetamine-like

psychostimulants) or with monoamine oxidase inhibitors, which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

Because of its pseudoephedrine content, this product may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bretylium, betanidine, guanethidine, debrisoquine, methyldopa, alpha- and beta- adrenergic blocking agents.

4.6. Pregnancy and Lactation

Pregnancy

There are no or limited amount of data from the use of Guaifenesin in pregnant women.

Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Insufficient information is available on the effects of administration of this product during human pregnancy. This product is not recommended during pregnancy and in women of childbearing potential not using contraception

Lactation

Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of Guaifenesin in new-borns/infants. A decision must be made whether to

discontinue breast-feeding or to discontinue/abstain from this product, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

4.7. Effects on ability to drive and use machines

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.

4.8. Undesirable effects

Serious adverse effects associated with the use of pseudoephedrine are extremely rare.

Symptoms of central nervous system excitation may occur, including sleep disturbance and, rarely, hallucinations.

Skin rashes, with or without irritation, have occasionally been reported with pseudoephedrine.

Urinary retention has been reported occasionally in men receiving pseudoephedrine; prostatic enlargement could have been an important factor.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9. Overdose

Symptoms and signs

The effects of acute toxicity from this product may include drowsiness, irritability, restlessness, tremor, palpitations, convulsions, hypertension, difficulty with micturition,
gastro-intestinal discomfort, nausea and vomiting.

Treatment

Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage may be undertaken if indicated. Catheterisation of the bladder may
be necessary. Acid diuresis can accelerate the elimination of pseudoephedrine, although the
potential therapeutic gain of this procedure is now in dispute. The value of dialysis in overdose is not known, although four hours of haemodialysis removed approximately 20 % of the total body load of pseudoephedrine in a combination product containing 60 mg pseudoephedrine and 8 mg acrivastine

5. Pharmacological properties

5.1. Pharmacodynamic properties

Pharmacotherapeutic Group: Cough and cold preparations, Expectorants. ATC Code:

R05CA10

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory decongestant. Pseudoephedrine is substantially less potent than ephedrine in

producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the central nervous system. Pseudoephedrine produces its decongestant effect within 30 minutes, persisting for at least 4 hours.

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

centres in the brain which in turn enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours.

Chlorphenamine is a potent antihistamine (H1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenmine include inhibition of histamine on smooth muscle, cappillary permeability and

hence reduction of oedma and wheal in hypersneitivity reactions such as allergy and anaphylaxis.

5.2. Pharmacokinetic properties

Absorption

Pseudoephedrine

Pseudoephedrine is well absorbed from the gut following oral administration. After the administration of one 60 mg pseudoephedrine tablet to healthy adult volunteers, the Cmax for pseudoephedrine was approximately 180 ng/ml with tmax occurring at approximately 1.5 - 2.0 hours.

Guaifenesin

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 micrograms/ml, with tmax occurring approximately 15 minutes after drug administration.

Chlorpheniramine

Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours

Distribution

The apparent volume of distribution of pseudoephedrine (Vd/F) was approximately 2.8 l/kg.

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

Metabolism and elimination

Pseudoephedrine
The t½ was approximately 5.5 hours. Pseudoephedrine is partly metabolised in the liver by Ndemethylation to norpseudoephedrine, an active metabolite. Pseudoephedrine and its metabolite are excreted in the urine; 55 % to 90 % of a dose is excreted unchanged. The apparent total body clearance of pseudoephedrine (Cl/F) was approximately 6 - 6.5 ml/min/kg. The rate of urinary elimination is accelerated when the urine is acidified.
Conversely, as the urine pH increases, the rate of urinary elimination is slowed.

Guaifenesin
Guaifenesin appears to undergo both oxidation and demethylation. Following an oral dose of 600 mg 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.
Chlorphenamine
Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Pharmacokinetics in Renal Impairment
Following the administration of a pseudoephedrine-containing product (8 mg acrivastine + 60mg pseudoephedrine) to patients with varying degrees of renal impairment, the Cmax for pseudoephedrine increased approximately 1.5-fold in patients with moderate to severe renal impairment when compared to the Cmax in healthy volunteers. The tmax was not affected by renal impairment. The t½ increased 3 to 12-fold in patients with mild to severe renal impairment respectively, when compared to the t½ in healthy volunteers.
There have been no specific studies of this product, or guaifenesin in renally impaired patients.
Pharmacokinetics in Hepatic Impairment
There have been no specific studies of this product, guaifenesin or pseudoephedrine in hepatic impairment.
Pharmacokinetics in the Elderly
After the administration of a pseudoephedrine-containing product (8 mg acrivastine + 60 mg pseudoephedrine) to elderly volunteers, the t½ for pseudoephedrine was 1.4-fold that seen in younger healthy volunteers. The apparent Cl/F was 0.8-fold that seen in younger healthy volunteers, and the Vd/F was essentially unchanged.
There have been no specific studies of this product, pseudoephedrine or guaifenesin in the elderly.

5.3. Preclinical Safety

The active ingredients of this product are well known constituents of medicinal products and their safety profiles are well documented. The results of pre-clinical studies do not add anything of relevance for therapeutic purposes.

6. Pharmaceutical Particulars

6.1. List of Excipients

Menthol
Methyl Paraben
Propyl Paraben
Sucrose
Hydroxyethyl Cellulose
(Natrosol HHX250)
Potassium Sorbate
Sunset Yellow FD & C Yellow 6 Colour (E110)
Carmosine colour (E122)
Sodium saccharin
Strawberry Flavour
Citric Acid Anhydrous
Vanilla flavour liquid
Alcohol 90%
(Rectified Spirit)
Purified water

6.2. Incompatibilities

None stated

6.3. Shelf-Life

24 Months

6.4. Special Precaution for storage

Stored below 300C, in a dry place. Protect from light. Keep out of reach of children.

6.5. Nature and contents of container

100mL glass bottles

6.6. Special Precautions for disposal and other handling

No special requirements
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

Regal Pharmaceuticals Limited

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8. Marketing Authorization Number

H2006/788/R1

9. Date of first authorization/renewal of the authorization

2026 March 17

10. Date of revision of the text

2026 March 17