

SMPC FOR TIXYCOF EXPECTORANT

1 NAME OF THE MEDICINAL PRODUCT

TIXYCOF EXPECTORANT

2 QUALITATIVE AND QUANTITATIVE COMPOSITION ACTIVE INGREDIENT

Each 5ml contains

Bromhexine hydrochloride 4.0mg

Diphenhydramine Hydrochloride 12.0mg

Ammonium Chloride 140mg

Sodium citrate 60mg

Menthol 1.5mg

For excipients see 6.1

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- Colds
- Hayfever
- Sneezing
- Coughing
- Itchy
- Watery red eyes
- Runny or blocked nose

4.2 Posology and method of administration

Children 2-6years: 2.5ml (1/2 teaspoonful) three times daily

6-12 years 5ml (1 teaspoonful) three times daily

Adult : 10-15ml (2-3 teaspoonful) three times daily or as directed by the Physician

SMPC FOR TIXYCOF EXPECTORANT

4.3 Contraindications

Alcohol: Avoid concomitant use of alcohol with this medication.

4.4 Special warnings and precautions for use

The Elderly: Caution is advised in the elderly as adverse effects may be more likely.

Driving and Hazardous work: This medication should be avoided as it may cause extreme sedation.

Alcohol: Avoid concomitant use of alcohol with this medication.

4.5 Interaction with other medicinal products and other forms of interaction

4.6 Pregnancy and lactation.

Potential risk to the foetus has been reported. Consult your doctor before use, or if you are planning to fall pregnant.

Breastfeeding:Avoid: It is unknown how this medication may affect your baby. Consult your doctor before use.

4.7 Effects on ability to drive and use machines

Driving and Hazardous work: This medication should be avoided as it may cause extreme sedation.

4.8 Undesirable effects Gastrointestinal disorders:

- Dry mouth
- Dizziness
- Headache
- Nausea/Vomitting
- Gastrointestinal discomfort.

4.9 Overdose

Porphyria:Avoid: It is unknown how this medication may affect your condition. Consult your doctor before use. **Infants and children:** this medication is not intended for use in children under the age of 6 years.

SMPC FOR TIXYCOF EXPECTORANT

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Diphenhydramine has anti-histaminic (H1-receptor), anti-emetic, anti-vertigo and sedative and hypnotic properties ¹². The anti-histamine action occurs by blocking the spasmogenic and congestive effects of histamine by competing with histamine for H1 receptor sites on effector cells, preventing but not reversing responses mediated by histamine alone ¹². Such receptor sites may be found in the gut, uterus, large blood vessels, bronchial muscles, and elsewhere ¹². Anti-emetic action is by inhibition at the medullary chemoreceptor trigger zone ¹². Anti-vertigo action is by a central antimuscarinic effect on the vestibular apparatus and the integrative vomiting center and medullary chemoreceptor trigger zone of the midbrain

Bromhexine is mucolytic agent used for a variety of respiratory conditions associated with increased mucus secretion. It is derived from the *Adhatoda vasica* plant and aids in the clearance of excess mucus, improving breathing and reducing cough. Ammonium chloride helps in loosening the congestion in the chest and throat, thereby making it easier to cough out phlegm through the mouth.

AMMONIUM CHLORIDE+DIPHENHYDRAMINE+MENTHOL+SODIUM CITRATE belongs to a class of medications called 'expectorants' used to treat cough. Coughing (dry or productive) is the body's way of clearing irritants (like allergens, mucus, or smoke) from airways and preventing infection. There are two types of coughs, namely: Dry cough and chesty cough. A dry cough is tickly and doesn't produce any vicious or thick mucus, while a chesty cough (wet cough) means mucous or sputum is produced to help clear your airways.

AMMONIUM CHLORIDE+DIPHENHYDRAMINE+MENTHOL+SODIUM CITRATE is a combination of four drugs, namely: Ammonium chloride (expectorants), Diphenhydramine (antihistamine), Sodium citrate (mucolytic), and menthol (cooling agent). Ammonium chloride belongs to the class of expectorants that works by increasing the volume of fluid in the airways, reduce the stickiness of mucus, and helps to remove it from airways. Diphenhydramine belongs to the class of antihistamines (anti-allergic drugs) that works by blocking the action of histamine, a substance responsible for causing allergic reactions. Sodium citrate is a mucolytic agent (cough/sputum thinner) that works by thinning and loosening phlegm (mucus) in the lungs, windpipe, and nose. Thereby, it helps to cough out easily. Menthol is a cooling agent that produces a cooling sensation and provides relief from minor throat irritation.

SMPC FOR TIXYCOF EXPECTORANT

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients Sucrose, Sodium methyl Paraben, Sodium Propyl Paraben, Etanol, Propylene glycol, flavour Saccharin sodium, Peagreen color,

6.2 Incompatibilities None stated.

6.3 Shelf life 3years

6.4 Special precautions for storage Do not store above 30°C.

6.5 Nature and contents of container Pinkish colored suspension in a pet bottle and a plastic cap

6.6 Special precautions for disposal None

7 MARKETING AUTHORISATION HOLDER : JEHYSON HEALTHCARE LTD

8. MARKETING AUTHORISATION NUMBER(S) NA

9 DATE OF FIRST AUTHORISATION: NA

10 DATE OF REVISION OF THE TEXT NA