

SMPC FOR GEE-KUF KIDS COUGH SYRUP

1 NAME OF THE MEDICINAL PRODUCT

TIXYCOF EXPECTORANT

2 QUALITATIVE AND QUANTITATIVE COMPOSITION ACTIVE INGREDIENT

Each 5ml contain

Diphenhydramine Hydrochloride 12.0mg

Sodium citrate 60mg

For excipients see 6.1

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

- soothes and relieves dry,

Tickly cough

4.2 Posology and method of administration

To be taken every three or four hours, 3 months- 1year 2.5ml to be taken

1-5years : 5ml to be taken

6-12years : 10ml to be taken three times daily or as directed by the Physician

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4.8 Undesirable effects Gastrointestinal disorders:

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

4.9 Overdose

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

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

AMMONIUM CHLORIDE+DIPHENHYDRAMINE+MENTHOL+SODIUM CITRATE is a combination of four drugs, namely: Ammonium chloride (expectorants), Diphenhydramine (antihistamine), Sodium citrate (mucolytic), and

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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.

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. MANUFACTURER: JEHYSON HEALTHCARE LIMITED

7 MARKETING AUTHORISATION HOLDER: GREENVINE
PHARMACEUTICAL LIMITED LTD

8. MARKETING AUTHORISATION NUMBER(S) NA

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9 DATE OF FIRST AUTHORISATION: NA

10 DATE OF REVISION OF THE TEXT NA