

PENDOREX COUGH MIXTURE SMPC

1. NAME OF THE MEDICINAL PRODUCT

PENDOREX COUGH MIXTURE

Strength: Each 10ml contains: Ammonium Chloride BP 200 mg, Sodium Citrate BP 100mg and Menthol 15.5mg, Squill Tincture BP

Pharmaceutical Form: Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Ammonium Chloride BP 110mg,

Sodium Citrate BP 40mg and

Menthol BP 1.1mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

AN amber syrupy liquid with a sweet taste and pleasant aroma and a burning sensation with pH of 4.0 to 6.0

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

5. PENDOREX COUGH MIXTURE is indicated for relief of bronchial congestion, colds and allergic bronchial congestion.

5.1 Posology and Method of Administration

Posology

As directed by the Physician OR Use six hourly as below:-

- 0 – 1 year: 2.5mls every 6 hours
- 1 – 5 years: 5mls every 6 hours
- 5 – 12 years: 7.5mls every 6 hours
- Adults: 10mls every 6 hours

Method of Administration

Oral Administration

4.3 Contraindications

PENDOREX COUGH MIXTURE is contraindicated with patients hypersensitive to any of the components of the formula.

PENDOREX COUGH MIXTURE is contraindicated to pregnant and breastfeeding mothers in high doses.

PENDOREX COUGH MIXTURE should not be given to patients with metabolic or respiratory alkalosis.

4.4 Special Warnings and Precautions for Use

PENDOREX COUGH MIXTURE should be given with extreme caution to patients with heart failure, oedema, renal impairment, hypertension and eclampsia.

Do not take PENDOREX COUGH MIXTURE and drive a car or operate machinery because it can cause drowsiness and dizziness.

Keep the medicine out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

PENDOREX COUGH MIXTURE may lead to enhanced sedation with other CNS depressant. It is incompatible with Calcium Chloride, Phenobarbitone and Kanamycin.

Alcoholic drinks and certain other central nervous system depressants such as anxiolytics or hypnotics can potentiate the sedative effects of Chlorpheniramine Maleate.

Ammonium Chloride Overdose

Overdosage of Ammonium Chloride has resulted in a serious degree of metabolic acidosis, disorientation, confusion and coma.

Treatment

Should metabolic acidosis occur following overdosage, the administration of an alkalinizing solution such as sodium bicarbonate or sodium lactate will serve to correct the acidosis.

Overdosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions.

Particulars of its Treatment

If overdose occurs the patient should be monitored for evidence of toxicity and standard symptomatic and supportive treatment applied as necessary.

6. PHARMACOLOGICAL PROPERTIES

6.1 Pharmacological Properties

Pharmacotherapeutic group and ATC Code

Pharmacotherapeutic group: **Antitussive and expectorant combination**

ATC Code: **R06AA02**

Mechanism of Action

Ammonium Chloride

It tends to lower the blood pH after being metabolized to urea and hydrochloric acid which provides hydrogen ions to acidify the blood or urine.

Sodium Citrate

It acts as an expectorant that thins the mucus.

Menthol

Menthol has mild local anaesthetic and decongestant properties.

Pharmacodynamic Effects

Ammonium Chloride

Ammonium chloride has irritant effect on mucous membrane and is considered to have expectorant properties.

Sodium Citrate

The effect of sodium citrate is that it renders the urine to become less acidic. It is an antitussive and mucolytic agent that breaks down the mucus so that coughing up phlegm becomes easier. It acts as an expectorant that thins the mucus.

Menthol

Menthol has mild local anaesthetic and decongestant properties.

6.2 Pharmacokinetic Properties

Ammonium Chloride

i. Absorption

Ammonium chloride is also absorbed by the gastrointestinal tract. Following oral administration, it is rapidly absorbed from the gastrointestinal tract whereby complete absorption occurs within 3 to 6 hours.

ii. Metabolism

In a test carried out on healthy male and female volunteers, they were orally administered with ammonium chloride. They produced transient increase in blood pH. Those who suffered from cirrhosis showed a greater and more prolonged increase over a higher baseline. This means that their livers metabolized ammonium chloride to form urea and hydrochloric acid.

iii. Excretion

Ammonium chloride is excreted by the kidneys in form of urine.

Sodium Citrate

i. Absorption and Excretion

Sodium citrate is absorbed and renally eliminated causing metabolic alkalosis and urinary alkalization in sufficient doses.

Menthol

i. Metabolism and Elimination

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.

6.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

7. PHARMACEUTICAL PARTICULARS

7.1 List of Excipients

Tartrazine Yellow Colour, Pineapple Flavour Liquid, Glycerine, Sodium Methyl Parabenzoate, Sodium Propyl Parabenzoate, Citric Acid, Rectified Spirit, Sugar Syrup and Purified Water

7.2 Incompatibilities

None known

7.3 Shelf life

36 months

7.4 Special precautions for storage

Store in a dry place below 30°C Protect from light

7.5 Nature and contents of container and special equipment for use, administration or implantation

PENDOREX COUGH MIXTURE is packed in 100ml amber coloured PET bottles that are sealed with 25mm ropp aluminium caps and labelled. Then the filled, sealed and labelled bottles are packed in unit cartons made of chipboard.

7.6 Special precautions for disposal and other handling

No special requirements

8 Marketing Authorization Holder:

MUCHIS HEALTHCARE LIMITED

5 Ogundana Street, Off Allien Avenue, Ikeja Lagos

Name of Manufacturer/Address: JEHYSON HEALTHCARE LIMITED

Jehyson crescent, 78km Lagos-Abeokuta Expressway Apomu, Ogun State