

1. NAME OF THE MEDICINAL PRODUCT

(COFTA TABLET) Ammonium Chloride BP, Ipecacuanha Liquid Extract BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cofta Tablet contains; Ammonium chloride BP 1mg, Ipecacuanha Liquid Extract BP 2.5µL, Liquorice Liquid Extract Powder BP 50mg, Peppermint oil BP 1µL, Aniseed oil BP 1µL.

(For a full list of actives and excipients, see section 6.1)

3. PHARMACEUTICAL FORM

Cofta Tablets are presented as brown, flat-sided, bedvelled edged, uncoated tablets with "Evans" engraved on one side and "Cofta" on the other side, aluminium foil – stripped in packs of 20's and 100's

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

"Cofta Tablet" is an expectorant for use in coughs with scanty secretions. Ipecacuanha and Ammonium chloride work in conjunction with Liquorice Extract and the essential oils of Cofta Tablets to soothe the throat, break up phlegm and provide symptomatic relief of coughs.

4.2 Posology and method of administration

Posology

Cofta Tablets are administered by oral route. The tablets are to be sucked slowly and should not be chewed or swallowed with fluid

Route of Administration: Oral

4.3 Contraindications

Contraindicated with known hypersensitivity to any of the ingredients of the product

4.4 Special warnings and precautions for use

Keep out of the reach of children. If symptoms persist, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Abacavir may decrease the excretion rate of Ammonium chloride which could result in a higher serum level. The risk or severity of hyperkalemia can be increased when Acebutolol is combined with Ammonium chloride. Aceclofenac may decrease the excretion rate of Ammonium chloride which could result in a higher serum level. Acemetacin may decrease the excretion rate of Ammonium chloride which could result in a higher serum level. Acetazolamide may increase the excretion rate of Ammonium chloride which could result in a lower serum level and potentially a reduction in efficacy.

The serum concentration of Acetylsalicylic acid can be increased when it is combined with Ammonium chloride. Ammonium chloride may decrease the excretion rate of Acridinium which could result in a higher serum level. Ammonium chloride may decrease the excretion rate of Acrivastine which could result in a higher serum level. Acyclovir may decrease the excretion rate of Ammonium chloride which could result in a higher serum level. Adefovir dipivoxil may decrease the excretion rate of Ammonium chloride which could result in a higher serum level.

4.6 Pregnancy and Lactation

The product is not associated with reports of teratogenicity. However, like other drugs, it should be administered with caution in the first trimester of pregnancy, unless the benefits outweigh the risks.

4.7 Effects on ability to drive and use machines

COFTA TABLET has no influence on the ability to drive and use machines.

4.8 Undesirable effects

None reported at recommended doses. In the event of overdose, vomiting, sweating and diarrhoea may be present.

4.9 Overdose

In extremely high doses, there may be reversible sodium retention and potassium loss leading to hypertension, water retention and electrolyte imbalance, particularly in patients with hypertension or circulatory disorders.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Expectorant

Mechanism of action

Ammonium chloride increases acidity by increasing the amount of hydrogen ion concentrations. Ammonium chloride can be used as an expectorant due to its irritative action on the bronchial mucosa. This effect causes the production of respiratory tract fluid which in order facilitates the effective cough.

5.2 Pharmacokinetic properties

COFTA TABLETS have been formulated using approved natural products. The tablets are intended to relieve the symptoms of cough.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Table 6.1: NAME AND FUNCTION OF EACH INGREDIENT

Raw Material
Ammonium Chloride BP
Ipecacuanha Liquid Extract
Sugar Granulated (milled)
Liquorice Extract BP Powder
Silicone Dioxide
Brown oxide Anstead 16192
Liquid Glucose Sulphur dioxide free
Gelatin BP Coarse Powder 160 bloom

6.2 Incompatibilities: Not applicable.

6.3 Shelf life: 3 years

6.4 Special precautions for storage

Store below 30°C away from light, Keep out of the reach of children

6.5 Nature and contents of container

Cofta Tablets are presented as brown, flat-sided, bedvelled edged, uncoated tablets with "Evans" engraved on one side and "Cofta" on the other side, aluminium foil – stripped in packs of 20's and 100's

6.6 Special precautions for disposal: No special requirements.

7. APPLICANT/MANUFACTURER

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