

## 1. NAME OF THE MEDICINAL PRODUCT

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

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Cofta Syrup contains; Ammonium chloride BP 30mg, Ipecacuanha Liquid Extract BP 10µL, Liquorice Liquid Extract Powder BP 50mg, Peppermint oil BP 6.9µL, Aniseed oil BP 2.6µL.

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

## 3. PHARMACEUTICAL FORM

Cofta Syrup is presented as a dark brown viscous liquid available in 60ml and 100ml PET bottles.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

“Cofta Syrup” 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 Syrup to soothe the throat, break up phlegm and provide symptomatic relief of coughs.

### 4.2 Posology and method of administration

#### Posology

Cofta Syrup is administered by oral route. The doses are to be taken three to four times daily

Children (Under one year): As directed by your physician

(1-12 years): 1-2 teaspoonfuls

Adults (12 years and above): 2-3 teaspoonfuls.

Shake the bottle before use.

**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 SYRUP 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 SYRUP has been formulated using approved natural products. The Syrup is 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**

<b>Raw Material</b>
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 Syrup is presented as a dark brown viscous liquid available in 60ml and 100ml PET bottles

**6.6 Special precautions for disposal:** No special requirements.

## 7. APPLICANT/MANUFACTURER

Evans Baroque Nigeria Limited,  
Km 32, Lagos – Badagry Expressway,  
Agbara Industrial Estate, Agbara,  
Ogun State, Nigeria.  
08033304149  
info@evansbaroque.com