

## **1. NAME OF THE MEDICINAL PRODUCT**

**1.1 Brand Name : UNODEX COUGH SYRUP**

**1.2 Generic Name : (Bromhexine Hydrochloride, Dextromethorphan Hydrobromide & Ammonium Chloride**

**1.3 Strength:** Each 10ml contains :

Bromhexine Hydrochloride BP 8 mg

Dextromethorphan Hydrobromide BP 10mg

Ammonium Chloride BP 100 mg

**1.4 Pharmaceutical Form:** Liquid Oral

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

### **Each 10ml contains:**

Bromhexine Hydrochloride BP 8 mg

Dextromethorphan Hydrobromide BP 10mg

Ammonium Chloride BP 100 mg

Flavoured mentholated syrupy base q.s

Colours : Brilliant Blue FCF & Quinoline

Yellow WS

## **3. PHARMACEUTICAL FORM:**

Oral solution

## **4. CLINICAL PARTICULARS**

### **4.1 THERAPEUTIC INDICATIONS:**

Cough with common cold

Acute and chronic bronchitis

Pertussis

Early pulmonary tuberculosis

Broncho Genic carcinoma and smoker's cough.

### **4.2 POSOLOGY AND METHOD OF ADMINISTRATION**

Adult: 2 tea spoonful to be taken 3-4 times a day

Children: ½ - 1 teaspoonful, 3-4 times a day

### **4.3 CONTRAINDICATIONS**

Contraindicated in individuals with known hypersensitivity to the product or any of its Components.

#### **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

Syrup should not be administered to patients with chronic or persistent cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician. There have been no specific studies in renal or hepatic dysfunction. Due to the extensive hepatic metabolism of dextromethorphan, caution should be exercised in the presence of hepatic impairment. Mucolytic, such as Bromhexine may disrupt the gastric mucosal barriers, Bromhexine should be used with care in patients with a history of peptic ulceration.

#### **4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS**

The concomitant use of a dextromethorphan containing product and monoamine oxidase inhibitors can occasionally result in symptoms such as hyperpyrexia, hallucinations, gross excitation or coma. Bromhexine may increase the concentration of concurrently administered antibiotics in bronchial secretions. No clinically relevant interactions with other medications have been reported

#### **4.6 PREGNANCY AND LACTATION**

Although it has been widespread use for many years without apparent ill consequence, there is insufficient information on the effect of administration during human pregnancy. In addition, it is not known whether excreted in breast milk.

#### **4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINE**

This medicine can impair cognitive function and can affect a patient's ability to drive safely.

#### **4.8 UNDESIRABLE EFFECTS**

Dizziness, Nausea, Vomiting, Gastrointestinal disturbance, Skin rash, Urticaria.

#### **4.9 OVERDOSE**

Signs and Symptoms

The effects of overdose may include drowsiness, lethargy, nystagmus, ataxia, respiratory depression, nausea, vomiting, and hyperactivity.

Treatment

Treatment should be symptomatic and supportive. Gastric lavage may be of use.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 PHARMACODYNAMICS PROPERTIES**

Dextromethorphan is a non-opioid antitussive drug. It exerts its antitussive activity by acting on the cough center in the medulla oblongata, raising the threshold for the cough reflex. Bromhexine is intended to support the body's mechanisms for clearing mucus from the respiratory tract. It is secretolytic, increasing the production of serous mucus in the respiratory tract and makes the phlegm thinner and less viscous. This contributes to a secret motoric effect by helping the cilia transport the phlegm out of the lungs. Menthol has local anesthetic and the counter irritant qualities, and it is widely used to relieve minor throat irritation. Ammonium Chloride is an electrolyte. It is the expectorant which thins mucus.

### **5.2 PHARMACOKINETIC PROPERTIES**

#### **Dextromethorphan**

##### **Absorption**

Dextromethorphan is well absorbed from the gut following oral administration.

##### **Distribution**

Due to extensive pre-systemic metabolism by the liver, detailed analysis of the distribution of orally administered dextromethorphan is not possible.

##### **Metabolism and Elimination**

Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites dextrophan (also known as 3-hydroxy-N-methylmorphinan) 3-hydroxymorphinan and 3methoxymorphinan have been identified as conjugated products in the urine. Dextrophan which also has antitussive action, is the main metabolite.

#### **Bromhexine Hydrochloride**

Absorption: Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract.

Distribution: It is widely distributed to body tissues and is highly bound to plasma proteins.

Metabolism: It undergoes extensive first pass metabolism in the liver.

Elimination: About 85 to 90% of a dose is excreted in the urine mainly as metabolites.

### **5.3 PRECLINICAL SAFETY DATA**

Not applicable

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 LIST OF EXCIPIENTS

Carmellose Sodium,	BP
Propylene Glycol	BP
Sorbital Solution 70%	BP
Sodium Benzoate	BP
Edetate Di-sodium	BP
Sucrose	BP
Col. Quinoline Yellow,	IH
Col. Brilliant Blue FCF	IH
Citric Acid Monohydrate	BP
Methanol	USP
Purified Water	IP/BP/USP/IH/Ph. Eur.

### 6.2 INCOMPATIBILITIES

Not applicable.

### 6.3 SHELF LIFE

24 Months

### 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 30°C. Protect from light.

### 6.5 NATURE AND CONTENTS OF CONTAINER

1 x 100 ml Amber PET Bottle.

### 6.6 SPECIAL PRECAUTION FOR DISPOSAL

Not Applicable

## 7. MARKETING AUTHORIZATION HOLDER

ame : UNOSOURCE PHARMA NIGERIA LIMITED,  
Address : # 47 Babapomile Street, Onipetesi  
Estate, Mangoro-Lagos, Nigeria.  
Phone : 002348038540440  
002348129126660  
E-mail : bennaworeogbokor@yahoo.com

## **NAME AND ADDRESS OF THE MANUFACTURER**

Name Akums Drugs & Pharmaceuticals Ltd.  
Address 22, Sector 6A, IIE, SIDCUL, Ranipur, Haridwar-249403,  
Uttarakhand, India.  
Phone 91-01334-325982  
E-mail [works@akums.in](mailto:works@akums.in)