



# **TUTOLIN LOZENGES** (Ipecacuanha Liquid Extract BP + Menthol Crystals USP)

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

**TUTOLIN LOZENGES**

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

Each lozenge contains:

Ipecacuanha Tincture .....2.5Ul

Menthol.....1.5mg

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Lozenge

A Brownish colour round shaped tablet lozenge.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Tutolin Lozenges is useful in the symptomatic relief and control of coughs. It has demulcent actions and helps promote the expulsion of secretions from the respiratory tract thereby reducing bronchial and nasal congestion.

### **4.2 Posology and method of administration**

#### **Adults and children 12 years and above**

2 to 4 Lozenges times daily.

#### **Children**

Not for Children below 5.

6-12 years: 1 lozenges twicw daily .

#### **Method of administration**

For oral administration.

### **4.3 Contraindications**

This product is contraindicated in individuals with known hypersensitivity to any of the components of the preparation listed in section 6.1.

The product is contra-indicated in patients who are hypersensitive to any of the components of the preparation and in neonates. It is also contra-indicated in patients with hepatic or renal impairment and in acute attacks of asthma.

### **4.4 Special warnings and precautions for use**

May cause drowsiness. If affected, do not drive or operate machinery.

Avoid alcoholic drinks.

Avoid taking on an empty stomach. Tutolin Lozenges when taken with food is well tolerated.

Large doses may produce an irritant effect on the gastric mucosa causing nausea, vomiting and diarrhoea.

### **4.5 Interaction with other medicinal products and other forms of interaction**

The action of ipecacuanha may be delayed or diminished if it is given with or after charcoal. Antiemetics may also diminish its effects.



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### **4.6 Fertility, pregnancy and lactation**

The product should be used with caution in pregnancy and lactation.

### **4.7 Effects on ability to drive and use machines**

May cause drowsiness. If affected, do not drive or operate machinery.

### **4.8 Undesirable effects**

Side effects are rare and usually mild and may be reduced by giving the drug with meals. Large doses have an irritant effect on the gastrointestinal tract and are reported to cause gastrointestinal disturbances like nausea, vomiting and diarrhoea.

The absorption of emetine which is most likely if vomiting does not occur after overdose of ipecacuanha, may give rise to adverse effects on the heart, such as conduction abnormalities or myocardial infarction. These combined with dehydration due to vomiting may cause vasomotor collapse followed by death.

### **4.9 Overdose**

Persistent bloody vomiting and bloody diarrhoea and mucosal erosions of the entire GIT has been reported following large doses of ipecacuanha.

#### Management:

After acute overdosage, activated charcoal should be given to delay absorption followed if necessary by gastric lavage. Further treatment should be symptomatic and along supportive lines

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

#### **Ipecacuanha:**

Ipecacuanha Extract is prepared from the dried underground organs of *Cephalis ipecacuanha* or of *C. acuminata*. It has been used as an expectorant in productive cough in doses of up to about 1.4mg of total alkaloids. It is used in larger doses as an emetic.

#### **Menthol:**

Menthol is either extracted from peppermint oil (which contains 30-50% concentration of menthol) or prepared synthetically. It is used chiefly to relieve symptoms of bronchitis, sinusitis and similar conditions. In small doses by mouth, menthol has a carminative action. It exerts a muscle relaxant action on the gut



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### **5.2 Pharmacokinetic properties**

#### **Menthol:**

After absorption, menthol is excreted in the urine and bile as a glucuronide.

### **5.3 Preclinical safety data**

None.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sucrose  
Aspartame  
Sodium Benzoate.  
Sorbitol Solution 70%  
Glycerol  
Sodium Carboxymethyl Cellulose  
Sweet Cherry Flavour  
FD & C Yellow No. 40 (Allura Red)  
Menthol Crystals  
Deionised Water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store below 30°C. Protect from light.

### **6.5 Nature and contents of container**

Pet bottles containing 100ml product placed in a printed carton.

### **6.6 Special precautions for disposal and other handling**

None.

## **7. APPLICANT/MANUFACTURER TUYIL PHARMACEUTICAL INDUSTRIES LIMITED**

NO 22, NEW YIDI ROAD ILORIN,  
KWARA STATE NIGERIA



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