

## Product Information

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### 1. Name of the Pharmaceutical Product

#### 1.1 Product name

ZECUF HERBAL COUGH REMEDY

#### 1.2 Each 10 mL Contains Extracts derived from:

Ocimum sanctum .....	100 mg
Glycyrrhiza glabra .....	60mg
Curcuma longa .....	50mg
Zingiber officinale.....	10mg
Adhatoda vasika .....	60mg
Solanum indicum.....	20mg
Inula racemose.....	20mg
Piper cubeba.....	10 mg
Terminalia belerica.....	20mg
Aloe barbadensis.....	50mg
&	
Menthol BP.....	6mg
Flavoured syrupy Base.....	q.s.

#### 1.3 Pharmaceutical Dosage Form

Oral syrup

### 2. Quality and Quantitative Composition

#### 2.1 Qualitative Declaration

**The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant**

Not Applicable.

#### 2.2 Quantitative Declaration

The active substance must be expressed per dosage unit

**Composition:**

<b>ZECUF HERBAL COUGH REMEDY</b>				
<b>FORMULA &amp; COMPOSITION</b>				
<b>Batch size: 10000 Liters</b>				
<b>Sr. No.</b>	<b>INGREDIENTS</b>	<b>GRADE</b>	<b>Category</b>	<b>QUANTITY (mg / 10ml)</b>
1.	Ocimum sanctum	In-house	Active	100mg
2.	Glycyrrhiza glabra	In-house	Active	60 mg
3.	Curcuma longa	In-house	Active	50 mg
4.	Zingiber officinale	In-house	Active	10 mg
5.	Adhatoda vasika	In-house	Active	60 mg
6.	Solanum indicum	In-house	Active	20 mg
7.	Inula racemosa	In-house	Active	20 mg
8.	Piper cubeba	In-house	Active	10mg
9.	Terminalia belerica	In-house	Active	20 mg
10.	Aloe barbadensis	In-house	Active	50 mg
11.	*Levomenthol	BP	Active	6 mg
12.	Sucrose	USP/BP	Sweetner	7500 mg
13.	Glycerol	BP	Humectant	500 mg
14.	Citric acid Monohydrate	BP	Buffering Agent	6.5 mg
15.	Sodium benzoate	BP	Preservative	35mg
16.	Sodium methyl Hydroxybenzoate	BP	Preservative	10mg
17.	Sodium propyl Hydroxy benzoate	BP	Preservative	5 mg
18.	Sorbic acid	BP	Preservative	5 mg
19.	Colour BQ Supra ( Green Q3427)	In-House	Colouring agent	6 mg
20.	Essence Pineapple	In-House	Flavouring agent	0.02 ml
21.	Purified water	BP	Vehicle	qs

\*Include 10% Overages

3.	<b>Pharmaceutical Form</b> Oral Syrup
4.	<b>Clinical particulars</b>
4.1	<b>Therapeutic indications</b> General cough, whooping cough in early stage, irritating and allergic cough, smokers cough, laryngitis, pharyngitis, tonsillitis and seasonal cough.
4.2	<b>Posology and method of administration</b> Adults: 1 to 2 teaspoonful three time daily  Children: ½ to 1 teaspoonful three time daily
4.3	<b>Contraindications</b> There are no known contraindications.
4.4	<b>Special warning and precautions for use</b> No data reported.
4.5	<b>Interaction with other medicinal products and other forms of interactions</b> No data reported.
4.6	<b>Undesirable effects:</b> No data reported.
4.7	<b>Effects on ability to drive and use machine</b> No data reported.
5.1	<b>Pharmacological properties:</b> <b>Pharmacology of Individual ingredients:</b>  <b>Ocimum Sanctum:</b> Tulsi has anti-catarhal, aromatic, demulcent and expectorant properties. Ocimum sanctum has demonstrated antimicrobial activity in invitro studies against M.tuberculosis and Staph aureus.  <b>Glycyrrhiza glabra:</b> Glycyrrhiza glabra has demulcent property in inflammatory condition or bronchial tubes providing relief in cough, sore throat, hoarseness of voice and asthma. It also possesses useful expectorant property.

	<p><b>Curcuma longa :</b> Curcuma longa brings about copious mucous discharge and instant relief in catarrh and coryza. It also relieves cough when consumed orally. Curcuma longa in various studies has demonstrated anti-inflammatory potential as well as lysosomal membrane stabilizing effect. Local application of Curcuma longa has accelerated healing by 23-24% in septic and aseptic wounds.</p> <p><b>Zingiber officinale :</b> Zingiber officinale has demonstrated anti-inflammatory activity in carragenin induced model of inflammation. It has also exhibited anti-rheumatic effect in various studies. In vitro experiments have demonstrated anti-histaminic activity of this plant.</p> <p><b>Adhatoda vasica:</b> The active alkaloid -vasicine and its autooxidant product Vasicinone have shown bronchodilator and antihistaminic effects. It has got antibacterial (against M. tuberculosis), thrombopoetic and uterine stimulant actions.</p> <p><b>Solanum indicum:</b> This ingredient is one of the ten roots which on to make Dasamulakwatha, a widely prescribed formulation in India. It is useful in asthma, dry cough, bronchitis and chronic fever. It is also indicated in bronchospasm.</p> <p><b>Piper cubeba :</b> Piper cubeba has expectorant property useful in acute and chronic bronchitis. Apart from beneficial action on cough, it is known to clear the throat and is much in demand by singers.</p> <p><b>Terminalia belerica :</b> Terminalia belerica possesses anti-inflammatory activity as demonstrated by its inhibitory effect on rat paw edema. It also possesses amoebicidal and antibacterial activity. Antibacterial activity has been demonstrated against Staphylococcus aureus, E. coli, Salmonella, Shigella, Klebsiella and Sarana lutea.</p> <p><b>Aloe barbadensis:</b> Aloe barbadensis has anti inflammatory and anti asthmatic actions.</p>
5.2	<p><b>Pharmacokinetics:</b> No data reported.</p>
5.3	<p><b>Preclinical Safety Data:</b> There is no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.</p>

## 6.0 Pharmaceutical Particulars

### 6.1 List of Excipients

Sr. No.	Ingredients	Pharmacopoeial status
1.	Sucrose	BP
2.	Glycerol	BP
3.	Citric acid monohydrate	BP
4.	Sodium Benzoate	BP
5.	Sodium Methyl Hydroxybenzoate	BP
6.	Sodium Propyl Hydroxybenzoate	BP
7.	Sorbic acid	BP
8.	Colour BQ Supra	Inhouse
9.	Flavour : Essence Pineapple	Inhouse
10.	Purified Water	BP

### 6.2 Incompatibilities:

Not applicable.

### 6.3 Shelf-life:

36 months

### 6.4 Special precautions for storage:

Store below 30°C. Do not freeze. Keep out of reach of children.

### 6.5 Nature and contents of container:

100 ml PET bottle. One such bottle is packed in a carton along with its packinsert.

## 7. Marketing Authorization Holder

**M/s. Unique Pharmaceuticals Laboratories,  
(A Division of J.B.Chemicals & Pharmaceuticals Limited),  
"Neelam Centre", B Wing, 4<sup>th</sup> Floor, Hind Cycle Road,  
Worli, Mumbai- 400 030, India.**

## 8 Marketing Authorization Numbers

Mfg. Lic. No. : GA/1425

## 9 Date of first Authorization / renewal of the Authorization

29.04.2001 / 01.01.2013

## 10 Date of revision of the text

Not applicable