

Legal Category  
POM: Prescription only medicine

- **SmPC**
- 

## 1. Name of the medicinal product

KRISTOLIN EXPECTORANT

## 2. Qualitative and quantitative composition

Each 5 ml solution contains

Diphenhydramine Hydrochloride BP 14 mg

Ammonium Chloride BP 140 mg

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Liquid Syrup

## 4. Clinical particulars

### 4.1 Therapeutic indications

**KRISTOLIN EXPECTORANT** is indicated for the relief of cough and associated congestive symptoms.

### 4.2 Posology and method of administration

For oral use

Adults and Children aged 12 years and over:

One 10 ml dose of syrup 4 times a day.

Maximum daily dose: 40 ml syrup.

### Children under 12 years:

**KRISTOLIN EXPECTORANT** is contraindicated in children under the age of 12 years.

The Elderly:

As for adults above (see Pharmacokinetics - The elderly).

Hepatic dysfunction

Caution should be exercised if moderate to severe hepatic dysfunction is present (see Pharmacokinetics - Hepatic dysfunction).

Renal dysfunction

It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure (see Pharmacokinetics - Renal dysfunction).

Do not exceed the stated dose.

Keep out of the reach and sight of children.

### 4.3 Contraindications

**KRISTOLIN EXPECTORANT** is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

KRISTOLIN EXPECTORANT is contraindicated in individuals with chronic or persistent cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by the physician.

KRISTOLIN EXPECTORANT should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOI) or those patients who have received treatment with MAOIs within the last two weeks.

Not to be used in children under the age of 12 years.

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

This product may cause drowsiness. If affected individuals should not drive or operate machinery.

Subjects with moderate to severe renal or hepatic dysfunction or urinary retention should exercise caution when using this product (see Pharmacokinetics - Renal/Hepatic Dysfunction).

This product contains diphenhydramine and therefore should not be taken by individuals with narrow-angle glaucoma or symptomatic prostatic hypertrophy.

Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

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

This product contains diphenhydramine and therefore may potentiate the effects of alcohol, codeine, antihistamines and other CNS depressants.

As diphenhydramine possesses some anticholinergic activity, the effects of anticholinergics (eg, some psychotropic drugs and atropine) may be potentiated by this product. This may result in tachycardia, dry mouth, gastrointestinal disturbances (eg, colic), urinary retention and headache.

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

Although diphenhydramine has been in widespread use for many years without ill consequence, it is known to cross the placenta and has been detected in breast milk. KRISTOLIN EXPECTORANT should therefore only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

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

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

#### **4.8 Undesirable effects**

Side effects associated with the use of KRISTOLIN EXPECTORANT are uncommon.

Diphenhydramine may cause: drowsiness; dizziness; gastrointestinal disturbance; dry mouth; nose and throat; difficulty in urination or blurred vision.

Less frequently it may cause palpitations, tremor, convulsions or parasthesia. Hypersensitivity reactions have been reported, in particular, skin rashes, erythema, urticaria and angioedema.

Adverse reactions to menthol at the low concentration present in KRISTOLIN EXPECTORANT are not anticipated.

#### **4.9 Overdose**

##### **Symptoms and signs**

The symptoms and signs of KRISTOLIN EXPECTORANT overdose may include drowsiness, hyperpyrexia and anticholinergic effects. With higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

##### **Treatment**

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with Syrup of Ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

#### **5. Pharmacological properties**

##### **5.1 Pharmacodynamic properties**

Antiallergic action: It produces its antihistamine action by competitively blocking H1 receptors. It binds to the H1 receptors present in the smooth muscles of the gastrointestinal tract, bronchi, large blood vessels and uterus and inhibit Histamine induced allergic symptoms. They do not inhibit the release of Histamine.

Antivertigo and antiemetic actions: Central antimuscarinic actions of antihistamines are responsible for these effects of Diphenhydramine.

Parkinsonism: Acetyl choline receptor antagonists are used for the treatment of Parkinsonism. Diphenhydramine reduces the unbalanced cholinergic activity in striatum of parkinsonian patients.

Antitussive action: Diphenhydramine suppresses the cough reflex by a direct effect on the cough centre.

Migraine: Diphenhydramine is used in migraine due to its sedative as well as antiemetic actions.

##### **5.2 Pharmacokinetic properties**

Absorption: It is well absorbed after oral administration. Distribution: Diphenhydramine is widely distributed in the body including CNS in protein bound form. Metabolism: It is extensively metabolised in the liver. Excretion: Excreted primarily in urine.

##### **5.3 Preclinical safety data**

None.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Sucrose BP  
Sodium Saccharin BP  
Sodium Citrate BP  
Citric Acid BP  
Sodium methyl paraben BP  
Sodium propyl paraben BP  
Colour amaranth  
Levomenthol BP  
Propylene Glycol BP  
Flavour Raspberry  
Distilled water

### **6.2 Incompatibilities**

There are no significant incompatibilities with the product.

### **6.3 Shelf life**

3 years.

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

Store in a cool dry place in the original package.

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

100 ml amber PET Bottle provided with a measuring cup.

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

No special requirements for disposal.

## **7. Marketing authorisation holder**

Krishat Pharma Industries Limited  
KM 15, Lagos-Ibadan Expressway,  
Ibadan, Oyo State,  
NIGERIA.  
Email: info@krishatpharma.com

## **8. Marketing authorisation number(s)**

NA

## **9. Date of first authorisation/renewal of the authorisation**

NA

## **10. Date of revision of the text**

NA

**Company contact details**

**Address**

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway,  
Ibadan, Oyo State,  
NIGERIA.

**Medical Information e-mail**

Email: [info@krishatpharma.com](mailto:info@krishatpharma.com)