Legal Category
POM: Prescription only medicine

- **SmPC**

1. Name of the medicinal product

KRISTOLIN CHILDREN COUGH SYRUP

2. Qualitative and quantitative composition

Each 5 ml solution contains
Diphenhydramine Hydrochloride BP 7 mg
Ammonium Chloride BP 70 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid Syrup

4. Clinical particulars

4.1 Therapeutic indications

KRISTOLIN CHILDREN COUGH SYRUP 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 CHILDREN COUGH SYRUP 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 CHILDREN COUGH SYRUP is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

KRISTOLIN CHILDREN COUGH SYRUP 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 CHILDREN COUGH SYRUP 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 sucrase-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 CHILDREN COUGH SYRUP 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 CHILDREN COUGH SYRUP 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 angiodema.

Adverse reactions to menthol at the low concentration present in KRISTOLIN CHILDREN COUGH SYRUP are not anticipated.

4.9 Overdose

Symptoms and signs

The symptoms and signs of KRISTOLIN CHILDREN COUGH SYRUP 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 antichlolinergic 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

2 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

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