



**PHARMACEUTICALS LIMITED**

## **DRUGFIELD PHARMACEUTICALS LIMITED**

**KOLDRIN-D® (Pseudoephedrine Hydrochloride 6mg,  
Chlorpheniramine Maleate 2mg, Ammonium Chloride 80mg)  
COUGH SYRUP (ADULT)**

### **SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)**

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

Koldrin-D® Cough Syrup (Adult)

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

Each 5ml contains Pseudoephedrine Hydrochloride 6mg, Chlorpheniramine Maleate 2mg, Ammonium Chloride 80mg.

(For a full list of excipients, see section 6.1).

## **3. PHARMACEUTICAL FORM**

Liquid - Syrup

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

- For the temporary relieve of these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
  - runny nose
  - sneezing
  - nasal congestion
  - itching of the nose or throat
  - itchy, watery eyes
- temporary relieve of these symptoms due to the common cold:
  - sinus congestion and pressure
  - runny nose
  - sneezing

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

Take this medication by mouth as directed by your doctor. If you are self-treating, follow all directions on the product package. If you have any questions, ask your doctor or pharmacist.

This medication may be taken with food if stomach upset occurs. Drink plenty of fluids unless otherwise directed by your doctor.

#### **Usual Adult dose**

10ml orally every 4 to 6 hours; not to exceed 4 doses per day (60ml/24hr).

### **4.3 Contraindications**

Koldrin-D® Cough Syrup (Adult) is contraindicated in patients with known allergy to any of the active ingredients;

If you are allergic or hypersensitivity to pseudoephedrine, Chlorpheniramine, Ammonium Chloride and Menthol.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine:**

- If you have high blood pressure or heart disease
- Taking medicines for depression known as monoamine oxidase inhibitors in the last 2 weeks.
- Diabetes and overactive thyroid gland (hyperthyroidism).
- Glaucoma (increase pressure in the eye).
- An enlarged prostate (this causes difficulty peeing or needing to pee often)
- Liver or kidney disease.
- In a child under 12 years of age to relieve cough and cold symptoms.

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

Shake well before use.

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

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines that may interact with Koldrin-D® Cough Syrup (Adult). These include:

- Medicines used to treat depression
- Medicines used to treat heart conditions
- Medicines used to treat high blood pressure
- Medicines used to treat urinary tract infections and bladder problems
- Medicines used to treat behavioural disorders
- Phenylephrine, a medicine used to treat congestion
- Appetite suppressants

**Taking Koldrin-D® Cough Syrup (Adult) with food and drink**

Limit caffeine intake (examples: coffee, teas, colas, chocolate and some herbal supplements) while taking Pseudoephedrine. Also avoid medicines containing additional Caffeine whenever possible. Side effects from Pseudoephedrine may get worse if you take excessive Caffeine. Taking a high amount of Caffeine can increase the risk of nausea, nervousness, palpitations, problems with sleep, rapid heartbeat, tremor, or other side effects.

Alcohol may interfere with the effect of this medicine. Avoid alcoholic drinks.

#### **4.6 Pregnancy and Lactation**

**Pregnancy**

Pseudoephedrine is not recommended in pregnancy because it can reduce the blood flow in the placenta and to the baby. There is some evidence that pseudoephedrine, taken in the first 12 weeks of pregnancy, may be associated with birth defects, although this evidence is not strong.

There is no good evidence that chlorpheniramine is harmful to your baby, but it can have side effects such as feeling drowsy.

Talk to your Doctor or Pharmacist before taking Koldrin –D<sup>®</sup> Cough Syrup (Adult).

### **Breastfeeding**

Although the small amounts of pseudoephedrine in breast milk are unlikely to harm the nursing infant, it may cause irritability occasionally. A single dose of pseudoephedrine decreases milk production acutely and repeated use seems to interfere with lactation. Mothers with new-borns whose lactation is not yet well established or in mothers who are having difficulties producing sufficient milk should not receive pseudoephedrine.

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

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you.

## **4.8 Undesirable effects**

The preparation is usually well tolerated but occasionally, there may be drowsiness, headache, nausea, vomiting.

## **4.9 Overdose**

### **Symptoms and signs**

The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

### **Treatment**

Treatment of pseudoephedrine toxicosis consists of decontamination, controlling the CNS and cardiovascular effects, and supportive care. Vomiting should be induced only in asymptomatic patients, followed by administration of activated charcoal with a cathartic.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamics properties**

#### **Chlorpheniramine Maleate**

**Pharmacotherapeutic group:** Antihistamines for Systemic use: ATC Code: R06AB04

#### **Chlorpheniramine Maleate**

Chlorpheniramine Maleate is an antihistamine, which acts by competing with histamine for H<sub>1</sub> receptor sites on effector cells. Chlorpheniramine also has anticholinergic activity, thereby prevent but do not reverse responses mediated by histamine alone.

#### **Pseudoephedrine**

Pseudoephedrine is a sympathomimetic agent with mostly  $\alpha$ -mimetic activity in comparison with the  $\beta$ -activity. Pseudoephedrine provides a nasal decongestant effect after oral administration due to its vasoconstrictive action. It has an indirect sympathomimetic effect due primarily to the release of adrenergic mediators from the post-ganglionic nerve endings.

**Ammonium Chloride**

Ammonium chloride has an irritant effect on mucous membranes and is considered to have expectorant properties.

**Menthol**

Menthol has mild local anaesthetic and decongestant properties.

**5.2 Pharmacokinetic properties****Pseudoephedrine**

Pseudoephedrine is rapidly and completely absorbed after oral administration and extensively distributed throughout the body with accumulation in the liver, lungs, kidneys, spleen and brain. Peak plasma concentrations are attained during therapy of 65-120 ug/ml, effective bronchodilator plasma levels are in the range 35-80 ug/m.

The plasma half life is reported to be between 3-11 hours, with up to 95% being excreted in the urine.

**Chlorpheniramine Maleate**

Well absorbed in the gastrointestinal tract following oral administration, peak plasma concentration are achieved in 2 to 3 hrs and effects usually last 4 to 6 hr; however, some of the drugs are much longer acting.

**Ammonium chloride**

Ammonium chloride is effectively absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver; the anion thus liberated into the bloodstream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine, this is followed by a transient diuresis.

**Menthol**

Menthol is hydroxylated in the liver by microsomal enzymes to p-methane -3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the glucuronide.

**5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

**6.0 PHARMACEUTICAL PARTICULARS****6.1 List of Excipients**

Citric Acid  
Sucrose  
Saccharin Sodium

Methyl Paraben  
Propyl Paraben  
Sodium Carboxyl Methyl Cellulose  
Alura Red  
Raspberry Essence  
Ethanol 96%  
Purified Water (To Volume)

## **6.2 Incompatibilities**

None have been reported or are known

## **6.3 Shelf life**

36 Months

## **6.4 Special precautions for storage**

Store below 30°C in tight container protected from light and moisture.

## **6.5 Nature and contents of container and special equipment for use, administration or implantation**

Koldrin-D® Cough Syrup (Adult) is red colored syrup free from particulate matter packaged and presented in 100ml amber bottles, capped with a metallic screw cap in chip hard board containers with a graduated spoon enclosed.

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

No special requirements.

## **7 APPLICANT/MANUFACTURER**

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