Summary Product Characteristics (SPC)

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1 Name of the product

Kofed Dry Cough Syrup

2. Qualitative and quantitative composition:

Each 5ml contains: Dextromethorphan HBr BP 7.5mg

3. Pharmaceutical form

Syrup

4. Clinical particulars

4.1 Therapeutic indications

Kofed Dry Cough Syrup is indicated for the treatment of conditions in which antitussive effects are desired. The preparation is used for the relief of dry and unproductive cough or if the cough is unduly tiring or hazardous.

4.2 Posology and method of administration:

Route of administration: Oral route

Kofed dry cough syrup is administered by oral route ever 4-6 hours at the dosage given below; or as the physician may deem necessary.

Adults: Two (5ml) spoonful 4 times a day.

Children:

2 to 5years: Take one 5ml spoonful three times a day

5 to 12 years: Take one 5ml spoonful and half three times a day

Under 2 years: Not recommended

Do not take more than 4 doses in 24 hours.

4.3 Contraindications:

This product is contraindicated in individuals with known hypersensitivity to the active substance or to any of the excipients.

This product is contraindicated in individuals who are taking, or have taken, monoamine oxidase inhibitors within the preceding two weeks.

Dextromethorphan, in common with other centrally acting antitussive agents, should not be given to subjects in, or at risk of developing respiratory failure.

This product is contraindicated in patients taking serotonin reuptake inhibitors.

4.4 Special warnings and precautions for use:

Kofed Dry Cough Syrup is contraindicated in patients with known history of hypersensitivity to one or more of the components in the preparation; and those with or at risk of developing respiratory failure.

Kofed Dry Cough Syrup should be avoided in patients receiving or who have taken monoannine oxidase inhibitors within the preceding two weeks because they may produce severe reactions; hyperpyrexia and fatalities have been reported.

4.5 Interaction with other medicinal products and other forms of interaction:

Dextromethorphan should not be used concurrently in patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment with MAOIs as there is a risk of serotonin syndrome (e.g. hyperpyrexia, hallucinations, gross

excitation or coma).
Dextromethorphan is primarily metabolised by the cytochrome P450 isoenzyme CYP2D6; the possibility of interactions with inhibitors of this enzyme, including amiodarone, haloperidol, propafenone, quinidine, SSRIs, and thioridazine, should be borne in mind.
Dextromethorphan might exhibit additive CNS depressant effects when co-administered with alcohol, antihistamines, psychotropics, and other CNS depressant drugs.

4.6 Fertility Pregnancy and lactation:

Unlikely to produce an effect.

4.7 Effects on ability to drive, operate machinery:

This medicine can impair cognitive function and can affect a patient's ability to drive safely.

4.8 Undesirable effects:

The adverse effects associated with Kofed Dry Cough Syrup include gastro-intestinal disturbances, skin rashes, dizziness, excitation, cofussion and respiratory depression may occur after overdosage

4.9 Overdose:

Signs and symptoms

Dextromethorphan is thought to be of low toxicity, but the effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs. Symptoms of overdose may include: mydriasis, nausea and vomiting, CNS depression, excitation, lethargy, nystagmus, psychomotor hyperactivity, serotonin syndrome, somnolence (drowsiness), dizziness, dysarthria (slurred speech), mental confusion, psychotic disorder (psychosis), and respiratory depression.

Management

Treatment should be symptomatic and supportive. Gastric lavage may be of use. Naloxone has been used successfully to reverse central or peripheral opioid effects of dextromethorphan in children (0.01mg/kg body weight).

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: R05DA09

Pharmacotherapeutic Group: Cough Suppressant

Kofed Dry Cough Syup contains Dextromethorphan in a formulation that makes it highly effective as an antitussive. Dextromethorphan is a cough suppressant which has central action on the cough centre in the medulla. Although structurally related to morphine, dextromethorphan has no analgesic properties and in general, it has little sedative activity. Dextrorphan, a metabolite of dextromethorphan also has some cough suppressant activity.

5.2 Pharmacokinetic properties

Dextromethorphan is rapidly absorbed form the gastrointestinal tract following oral administration. It is metabolized in the liver and excrated in the urine as the unchanged drug and also as demethylated metabolites including dextrorphan which has some antitussive activity

5.3 Preclinical safety data

General toxicology

Acute oral toxicity studies conducted with Dextromethorphan report the following LD_{50} values (mg/kg): mouse, 210 and rat, 116. Acute subcutaneous toxicity with Dextromethorphan reports the LD_{50} value (mg/kg): mouse, 112. Acute intravenous toxicity with Dextromethorphan reports the LD_{50} value (mg/kg): rat, 16.3.

Repeat dose toxicity studies conducted in rats for 13 weeks duration at doses up

to 100 mg/kg and 27 weeks at 10 mg/kg, and of 14 weeks in dogs by oral gavage at doses up to 4 mg/kg on five days per week. The only effect recorded was of reduced body weight gain in the rat 13-week study at the highest dose.

Genetic Toxicology

Dextromethorphan hydrobromide was negative in the bacterial reverse mutation assay (Ames test). Dextromethorphan 39 mg/kg is reported to be negative in *in-vivo* mouse micronucleus test and comet assay. Dextromethorphan was reported to be negative in *in vitro* chromosome aberration assay tested up to 200 µg/ml.

Carcinogenicity

There are no known reports of animal carcinogenicity studies for Dextromethorphan. The overall weight of evidence for Dextromethorphan and its structural analogues, support the conclusion that this class of phenanthrene-based chemicals, and Dextromethorphan, in particular, are not genotoxic in vitro or in vivo

Teratogenicity

There was no association between dextromethorphan and malformations.

Fertility

Mating, gestation, fertility, littering and lactation were studied in rats at doses up to 50 mg/kg and no adverse effects were found.

6. Pharmaceutical particulars:

6.1List of excipients:

Hydroxyethyl cellulose
Sodium Benzoate
Potassium Sorbate
Propylene Glycol
Sodium Saccharin
Menthol Crystals
Citric Acid
Chocolate Brown Colour
Vanilla Essence Liquid
Purified Water

6.2 Incompatibilities:

None known

6.3 Shelf life:

30 months

6.4 Special precautions for storage:

Store below 30°C

6.5 Nature and contents of the container:

100ml Amber coloured PET bottle

6.6 Special precautions for disposal:

No special requirements

7. Registrant:

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