

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINAL PRODUCT

D-KOFF EXPECTORANT
100MLS COUGH EXPECTORANT SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml syrup contains:

Diphenhydramine Hydrochloride BP... 10 mg
Bromhexine Hydrochloride BP... 4.0 mg
Ammonium Chloride BP... 138 mg
Sodium Citrate BP... 58 mg Menthol
BP ... 1.5 mg

3. PHARMACEUTICAL FORM

Syrup

A dark brown coloured syrup with a pleasant taste and menthol odour, packed in a 100 ml

Amber glass bottle with 28 mm printed pp caps.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic relief of Cough and nasal Congestion. Also relief of perennial and seasonal allergic rhinitis, vasomotor rhinitis and allergic conjunctivitis, temporary relief of runny nose and sneezing caused by common cold.

4.2 Posology and method of administration

Adults: 10ml to be taken every 4 -6 hours, not exceeding 50 ml / day

Children 6 - 12 years: 5 ml to be taken every 4 - 6 hours

Children 2 to 6 years: 2.5 ml to be taken every 4 - 6 hours

4.3 Contraindications:

Contraindicated in patients with a known hypersensitivity towards any ingredient of the product.

Pregnancy: Avoid: Potential risk to the foetus has been reported. Consult your doctor before use, or if you are planning to fall pregnant.

Breastfeeding: Avoid: It is unknown how this medication may affect your baby.

Consult your doctor before use.

Porphyria: Avoid: It is unknown how this medication may affect your condition. Consult your doctor before use. Infants and children: this medication is not intended for use in children under the age of 6 years.

4.4 Special warnings and precautions for use:

The Elderly: Caution is advised in the elderly as adverse effects may be more likely.

Driving and Hazardous work: This medication should be avoided as it may cause extreme sedation.

Alcohol: Avoid concomitant use of alcohol with this medication

4.5 Interaction with other medicinal products and other forms of interaction

- Alcohol, drugs for anxiety and sleeping tablets if co-administered along with the medication lead to enhanced sedation.

- Monoamine oxidase inhibitors and tricyclic antidepressants increase the occurrence of Diphenhydramine relating side-effects.

Disease Interactions: Consult your doctor before using this drug if you have asthma, liver or kidney disease, glaucoma, epilepsy, a heart rhythm disturbance, an enlarged prostate, difficulty urinating, or if you have been diagnosed with myasthenia gravis.

4.6 Pregnancy and lactation

Pregnancy

Data on a limited number of exposed pregnancies indicate no adverse effects of amoxicillin on pregnancy or on the health of the foetus/new-born child. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or

indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

Breast-feeding

Breastfeeding: avoid. It is unknown how this medication may affect your baby.

Consult your doctor before use.

Porphyria: avoid. It is unknown how this medication may affect your condition.

Consult your doctor before use.

Infants and children: this medication is not intended for use in children under the age of 6 years.

The elderly: caution is advised in the elderly as adverse effects may be more likely.

4.7 Effects on ability to drive and use machines this medication

should be avoided as it may cause extreme sedation.

4.8 Undesirable effects

Side Effect	Frequency		Consult your doctor	
	Common	Rare	Only if severe	In all cases
dry mouth	X		X	
drowsiness	X		X	
dizziness		X	X	
headaches		X	X	
nausea/vomiting		X	X	
anxiety		X		X
shortness of breath		X	X	
muscle weakness		X		X
heart palpitations		X		X

In addition to its intended effect, D-koff Cough Expectorant may cause some unwanted effects too. In such cases, you must seek medical attention immediately. This is not an exhaustive list of side effects. Please inform your doctor if you experience any adverse reaction to the medication.

Cough

Respiratory tract inflammation
Musculoskeletal (bone muscle
or joint) pain Respiratory tract
infection Throat irritation.

4.9 Overdose

A small overdose is no cause for concern. In case of intentional large overdose, seek emergency medical attention.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Diphenhydramine Hydrochloride, Sodium Citrate, Ammonium Chloride and Menthol is an antitussive and expectorant cough mixture. Antitussives are used to suppress or relieve/soothe coughing, while expectorants stimulate the respiratory tract to increase the production of bronchial secretions. This then thins mucus, facilitating the expulsion of phlegm or mucus from the respiratory tract. Diphenhydramine is an antihistamine that relieves congestion and post-nasal drips, while Ammonium Chloride is the expectorant which thins mucus. Sodium citrate is a mucolytic, an agent which breaks down mucus, so that coughing up phlegm is easier. Menthol is an expectorant.

Relax cough syrup, a combination of Diphenhydramine Hydrochloride, Sodium Citrate and Ammonium Chloride, is an antitussive and expectorant cough mixture. Diphenhydramine is an antihistamine that relieves congestion and post-nasal drips. Ammonium Chloride is the expectorant which thins mucus. Sodium Citrate is a mucolytic, an agent which breaks down mucus, so that coughing up phlegm is easy.

5.2 Pharmacokinetic properties

Absorption: Quickly absorbed with maximum activity occurring in approximately one hour.

Protein Binding: 98 to 99%

Metabolism: Hepatic and renal

Route of Elimination: Little, if any, is excreted unchanged in the urine; most appears as the degradation products of metabolic transformation in the liver, which are almost completely excreted within 24 hours.

Half Life: 1-4 hours.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6. Pharmaceutical particulars

6.1 List of excipients

Sugar

Disodium EDTA

Methyl paraben

Propyl paraben

Sodium Benzoate

Ammonium Chloride

Bromerol

Caramel

Glycerin

Liquid glucose

Propylene Glycol

Sodium citrate

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage Store in cool and dry place, Temperature below 30°C. Protect from Moisture.

6.5 Nature and contents of container

100 ml Amber glass Bottle with 28 mm Printed PP caps

7. APPLICANT/MANUFACTURER

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