

PRODUCT: STOPKOF -P SYRUP
(Pediatric Cough Syrup 100 ml)

MODULE 1 REGIONAL ADMINISTRATIVE INFORMATION

SECTION 1.3 PRODUCT INFORMATION

SUB SECTION 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

2.3 Quality Overall Summary

1. NAME OF THE MEDICINAL PRODUCT

Stopkof-P Syrup 100 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains Diphenhydramine Hydrochloride 7.0 mg

Sr. No	Ingredients	Quantity (mg/ 5 ml)	Function of Ingredients
1	Diphenhydramine Hydrochloride	7.0 mg	Active
2	Sugar	742.50 mg	Sweetening agent / syrup base
3	Sodium Benzoate	25.00 mg	Preservative
4	Sodium Saccharin	15.00 mg	Sweetening agent
5	Sodium Citrate	28.50 mg	pH adjustment
6	Glycerin	0.156 ml	Demulscant
7	Liquid Glucose	2.494 mg	Anti-crystallizing agent
8	Menthol	0.550 mg	Flavouring agent
9	Propylene Glycol	0.259 ml	Vehicle
10	Citric Acid Anhydrous (For pH Adjustment)	q.s.	pH adjustment
11	Trisodium Citrate Dihydrate (For pH Adjustment)	q.s.	pH adjustment
12	Soluble Essence Cherry	0.010 ml	Flavour
13	Purified Water q.s. To Make Volume	q.s. to 5 ml	Vehicle

PRODUCT: STOPKOF -P SYRUP

(Pediatric Cough Syrup 100 ml)

MODULE 1 REGIONAL ADMINISTRATIVE INFORMATION

SECTION 1.3 PRODUCT INFORMATION

SUB SECTION 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

3. PHARMACEUTICAL FORM

Colourless to pale yellow syrupy liquid with pleasant odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

Stopkof-P syrup is indicated for the relief of cough and its congestive symptoms, runny nose and sneezing, and in the treatment of hay fever and other allergic conditions affecting the upper respiratory tract. It is specially formulated for children and contains no artificial dyes or sucrose.

4.2 Posology and Method of Administration

Children under 6 years:

Stopkof-P syrup is contraindicated in children under the age of 6 years (see section 4.3).

Children 6 to 12 years:

Two 5 ml spoonfuls every 6 hours

No **more** than four doses should be given in any 24 hours.

Not to be used for more than five days without the advice of a doctor. Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

Do not exceed the stated dose.

Keep out of the reach and sight of children.

Route of Administration: Oral

4.3 Contraindications

Stopkof-P syrup is contraindicated in individuals with known hypersensitivity to the product or any of its constituents.

Stopkof-P 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 (see section 4.5).

Not to be used in children under the age of 6 years.

PRODUCT: STOPKOF -P SYRUP (Pediatric Cough Syrup 100 ml)

MODULE 1 REGIONAL ADMINISTRATIVE INFORMATION

SECTION 1.3 PRODUCT INFORMATION

SUB SECTION 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

4.4 Special warnings and precautions for use

Diphenhydramine should not be taken by patients with susceptibility to angle-closure glaucoma or symptomatic prostatic hypertrophy unless directed by a doctor.

Alcohol or other potential sedating **medicines** should not be used concurrently with Diphenhydramine.

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

The product may cause drowsiness. This product should not be used to sedate a child.

The label will state:

Do not use to sedate a child.

Do not exceed the stated dose.

Do not take with any other cough and cold medicine.

Ask a doctor before use if your child suffers from a chronic or persistent cough, if he/she has asthma, is suffering from an acute asthma attack or where cough is accompanied by excessive secretions.

4.5 Interaction with other medicinal products and other forms of interaction

CNS depressants: may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol.

Antimuscarinic drugs: may have an additive muscarinic action with other drugs, such as atropine and some antidepressants.

MAOIs: Not to be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

4.6 Fertility, pregnancy and lactation

Diphenhydramine crosses the placenta and has been detected in breast milk.

Stopkof-P syrup should only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

PRODUCT: STOPKOF -P SYRUP

(Pediatric Cough Syrup 100 ml)

MODULE 1 REGIONAL ADMINISTRATIVE INFORMATION

SECTION 1.3 PRODUCT INFORMATION

SUB SECTION 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

4.7 Effects on ability to drive and use machines

This preparation may cause drowsiness, dizziness or blurred vision. If affected, the patient should not drive or operate machinery.

4.8 Undesirable effects

Common side effects:

CNS effects: Drowsiness (usually diminishes within a few days), paradoxical stimulation, headache, psychomotor impairment.

Antimuscarinic effects: Urinary retention, dry mouth, blurred vision, gastrointestinal disturbances, thickened respiratory tract secretions.

Rare side effects:

Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

Adverse reactions to menthol at the low concentration present in Stopkof-P syrup are not anticipated.

4.9 Overdose

Signs and Symptoms:

Drowsiness, hyperpyrexia and anticholinergic effects. In children, CNS excitation, including hallucinations and convulsions may appear; with larger doses, coma or cardiovascular collapse may follow.

Treatment

Treatment of overdose with Stopkof-P syrup is likely to involve supportive care and rapid gastric emptying with syrup of Ipecac induced emesis or gastric lavage. In cases of acute poisoning, activated charcoal may be useful. Seizures may be controlled with Diazepam or Thiopental Sodium. In addition to supportive care, the intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Diphenhydramine is a potent antihistamine and antitussive with anticholinergic properties. Recent experiments have shown that the antitussive action is discrete from H₁-receptor blockade and is located in the brain stem.

Menthol has mild local anaesthetic and decongestant properties.

PRODUCT: STOPKOF -P SYRUP (Pediatric Cough Syrup 100 ml)

MODULE 1 REGIONAL ADMINISTRATIVE INFORMATION

SECTION 1.3 PRODUCT INFORMATION

SUB SECTION 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

5.2 Pharmacokinetic properties

Diphenhydramine is well absorbed from the gastrointestinal tract. Peak serum levels are reached at between 2-2.5 hours after an oral dose. Duration of activity is between 4 - 8 hours. The drug is widely distributed throughout the body, including the CNS, and some 78% is bound to plasma proteins. Estimates of the volume of distribution lie in the range 3.3 - 6.8 l/kg.

Diphenhydramine experiences extensive first-pass **metabolism**, undergoing two successive N-Demethylations; the resultant amine is then oxidised to a carboxylic acid. Values for plasma clearance lie in the range 600 - 1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine.

Pharmacokinetic studies in elderly subjects indicate no major differences in drug distribution or elimination compared with younger adults.

Menthol: After absorption, menthol is conjugated in the liver and excreted both in urine and bile as the glucuronide.

Renal Dysfunction

The results of a review on the use of diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

Hepatic Dysfunction

After intravenous administration of 0.8 mg/kg diphenhydramine, a prolonged half-life was noted in patients with chronic **liver disease** which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

5.3 Preclinical safety data

Not applicable

6. Pharmaceutical particulars

6.1 List of excipients

Sugar

Sodium Benzoate

Sodium Saccharine

**PRODUCT: STOPKOF -P SYRUP
(Pediatric Cough Syrup 100 ml)**

MODULE 1 REGIONAL ADMINISTRATIVE INFORMATION

SECTION 1.3 PRODUCT INFORMATION

SUB SECTION 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Sodium citrate

Glycerin

Liquid glucose

Menthol

Propylene glycol

Citric acid anhydrous (For pH adjustment)

Trisodium citrate dihydrate (For pH adjustment)

Soluble Essence cherry

Purified water q.s to make volume

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C, protected from light.

6.5 Nature and contents of container

100 ml amber glass bottle sealed with plastic caps having PE wads.

6.6 Special precautions for disposal and other handling

No special requirements for storage.

7. Marketing authorization holder

National Pharmaceutical Industries Co. (SAOG)

P.O Box 120,

Postal Code 124

Rusayl, Sultanate of Oman