

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

SHALTOUX 4 WAY RELIEF (Diphenhydramine Hydrochloride, Ammonium Chloride, Sodium Citrate & Menthol Cough Expectorant)

2. Qualitative and quantitative composition

2-(Diphenylmethoxy)-N,Ndimethylethanamine hydrochloride. 14.00 mg

Ammonium Chloride 135.00 mg

Trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate. 57.00 mg

Excipients of known effect: propylene glycol

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Syrup (Oral Liquid)

4. Clinical particulars

4.1 Therapeutic indications

Shaltoux Cough Syrup is a cough expectorant that contains diphenhydramine hydrochloride, ammonium chloride, sodium citrate and menthol. Shaltoux Cough Syrup is used to treat wet or productive cough. The combination of all these components relieves cough, sneezing and blockage of nose that occur in common cold, allergy or bronchitis (swelling of the bronchial tubes) or inhaled irritants.

4.2 Posology and method of administration

Adult and children over 12 years: Take 2-3 teaspoonfuls (10-15 ml) every four to six hours.

Children 6-12 years old: Take 1-1.5 teaspoonfuls (5-7.5 ml) every four to six hours.

Method of administration: Oral

4.3 Contraindications

- Aggravated Closed angle glaucoma (increased pressure in eye).
- Aggravated inability to pass urine.
- Age less than 6 years.
- Taking alcohol or other medicines (CNS depressants, barbiturates and tranquilizers) affecting the brain functions.
- Allergy to any of the constituents of Shaltoux Cough Syrup

4.4 Special warnings and precautions for use

Pregnancy – Shaltoux Cough Syrup when you are pregnant or breast-feeding. It can be used in pregnancy when the expected benefit to the mother is more than the risk to the fetus.

4.5 Interaction with other medicinal products and other forms of interaction

Phenothiazines, benzodiazepines, monoamine oxidase inhibitors, tricyclic antidepressants.

4.6 Pregnancy and Lactation

Shaltoux Cough Syrup when you are pregnant or breast-feeding. It can be used in pregnancy when the expected benefit to the mother is more than the risk to the fetus.

4.7 Effects on ability to drive and use machines

Be careful driving or operating machinery because Shaltoux Cough Syrup may cause impairment in the mental alertness.

4.8 Undesirable effects

SHALTOUX COUGH SYRUP is well-tolerated in majority of patients. It may cause excessive sleepiness.

4.9 Overdose

Symptoms of over dosage include dry mouth, headache, nausea, tachycardia (increased heart beat) and inability to pass urine. Contact your health care provider immediately and say exactly how much you have taken. Your health care provider will advise you what to do. It is important to contact your health care provider even if you feel well.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Components in Shaltoux Cough Syrup have the following actions

- Diphenhydramine reduces the action of histamine. Diphenhydramine suppresses the allergic effects of histamine and it also reduces irritation of inner lining and secretions in the respiratory tract.
- Ammonium chloride and sodium citrate are expectorant that help in the expulsion of sputum.
- Menthol provides the soothing effect in respiratory tract.

5.2 Pharmacokinetic properties

Diphenhydramine: Oral absorption - > 90%, Pre-systemic metabolism - 50%, Plasma half-life range - 2.4 to 8 hours (Mean 3.3 hours), Volume of distribution - 3.28 l/kg, Plasma protein binding 85% – 98%.

5.3 Preclinical safety data

No additional data of relevance.

6. Pharmaceutical Particulars

6.1 List of Excipients

Methyl paraben BP, propyl paraben BP, sugar, sorbitol 70% non-crystallising BP, propylene glycol BP, glycerin BP and citric acid monohydrate BP. Colour: Caramel. Flavor - Mix Fruit & Cool-mint.

6.2 Incompatibilities

None

6.3 Shelf-Life

36 months.

6.4 Special Precautions for storage

Do not store above 30°C. Protect from the sunlight. Do not refrigerate. Keep out of the reach of children. Do not use Shaltoux Cough Syrup after the expiry date which is stated on the pack.

6.5 Nature and Content of container

Dark brown coloured syrup, filled in labeled 100 mL amber coloured PET bottle.

6.6 Special precautions for disposal and other handling

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Marketing Authorization Holder

SHALINA HEALTHCARE DMCC
30th Floor, Almas Towers,
Jumeirah Lakes Towers Dubai-UAE.

8. Marketing Authorization Number

CTD8435

9. Date of first authorization/renewal of the authorization

02/05/2024

10. Date of revision of the text

12/05/2025