Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Shaltoux 4 Way Relief Syrup

2. Qualitative and quantitative composition
Each 5 mL contains:
Diphenhydramine Hydrochloride.... 14.00 mg
Ammonium Chloride.....135.00 mg
Sodium Citrate .....57.00 mg
Menthol.....1.21 mg

For a full list of excipients, see section 6.1

3. Pharmaceutical form
Syrup (Oral Liquid)

4. Clinical particulars

4.1 Therapeutic indications
Relieves cough, sneezing, nasal congestion due to throat & bronchial irritation as may occur with common cold, allergy and bronchitis or inhaled irritants.

4.2 Posology and method of administration
Adult: 1-2 teaspoonful, Children >2yr: ½-1 teaspoonful. To be taken every 4-6 hours, or as directed by the physician.

Method of administration: Oral

4.3 Contraindications
Closed angle glaucoma & urinary retention is aggravated. Concomitant consumption of alcohol, CNS depressants, barbiturates and tranquilizers.

4.4 Special warnings and precautions for use
Special precautions, especially during pregnancy and lactation, precautions use by children or the elderly and in particular pathological circumstances. If necessary, special precautions to be taken by persons handling the drug and administering them to patients and the precautions that must eventually be taken by the patient:

Children – Contraindicated in children less than 2 years.
Pregnancy –Should be used only if clearly needed.
Nursing Mothers – Diphenhydramine is excreted in breast milk but this has not been quantified.

4.5 Interaction with other medicinal products and other forms of interaction

Phenothiazine derivatives, benzodiazepines, MAOIs, tricyclic antidepressants

4.6 Pregnancy and Lactation

Pregnancy –Should be used only if clearly needed.

Nursing Mothers – Diphenhydramine is excreted in breast milk but this has not been quantified.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Drowsiness

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9 Overdose

Symptoms of over dosage include dry mouth, headache, nausea, tachycardia and urinary retention. Best treated with gastric lavage and supportive measures.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Diphenhydramine blocks the effects of the naturally occurring chemical histamine in the body and thus reduces mucosal irritation & mucus secretion. Ammonium Chloride and Sodium Citrate are saline expectorants & their expectorant action is caused by irritation of the bronchial mucosa. Menthol is a powerful expectorant and demulcent.

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

Diphenhydramine blocks the effects of the naturally occurring chemical histamine in the body and thus reduces mucosal irritation & mucus secretion. Ammonium Chloride and Sodium Citrate are saline expectorants & their expectorant action is caused by irritation of the bronchial mucosa. Menthol is a powerful expectorant and demulcent. Pharmacotherapeutic Group: Cough expectorant used to treat wet or productive cough.

6. Pharmaceutical Particulars

6.1 List of Excipients

Glycerin BP

Sorbitol 70 % Non-crystallizing BP
Propylene Glycol BP
Methyl Hydroxybenzoate (Methyl paraben) BP
Propyl Hydroxybenzoate (Propyl paraben) BP
Citric Acid Monohydrate BP
Sugar S 30
Flavour Mixed Fruit (Liquid)
Flavour Coolmint "S"
Colour Caramel
Purified Water BP

6.2 Incompatibilities
Not applicable

6.3 Shelf-Life
36 months

6.4 Special Precautions for storage
Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and Content of container
100 mL Amber PET Bottles with 10 mL measuring cap

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing Authorization Holder
Shalina Healthcare DMCC, Dubai-UAE
30th Floor, Almas Towers, Jumeirah Lakes Towers Dubai-UAE.

8. Marketing Authorization Number
H2024/CTD8435/18283

9. Date of first authorization/renewal of the authorization
21/05/2024

10. Date of revision of the text
21/05/2024