

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SUPERIL LOZENGES WITH HONEY-LEMON FLAVOUR

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lozenge Contains:

2, 4-Dichlorobenzyl Alcohol (In-house)	1.2 mg
Amylmetacresol BP	0.6 mg

3. PHARMACEUTICAL FORM

Lozenges

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Naso-pharyngeal and bucco-pharyngeal antiseptic. Symptomatic relief of sore throat.

4.2 Posology and method of administration

One lozenge to be sucked in the mouth every two to three hours. Not to exceed eight lozenges in 24 hours. Not recommended for children under 12 years.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and special precautions for use

It should be used with caution in epilepsy, impaired cardiac conduction, shock, liver damage. Consult your doctor before use if you are pregnant or nursing mother.

When a sore throat persists for more than two days, or is accompanied by headache, nausea or vomiting consults your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

If pregnant or breast feeding consult your doctor before using this product. Do not exceed the stated dose.

4.7 Effects on ability to drive and use machines

Normal use of the product is not known to have any effects on ability to drive or use machines.

4.8 Undesirable effects

No side effects have been observed when the formulation is used as indicated and in the recommended doses.

4.9 Overdose

Treatment is supportive and symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Superil Lozenges has antibacterial properties.

5.2 Preclinical safety data

Pre-clinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not already been mentioned elsewhere in this summary.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

SUPERIL LOZENGES WITH HONEY-LEMON FLAVOUR

Sucrose NF

Liquid Glucose BP

Colour Sunset Yellow (E110) (In-house)

Caramel NF

Mentha Oil (In-house)

Honey Flavour (In-house)

Essence Lemon Oil (In-house)

Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place.

Keep out of reach of children

6.5 Nature and contents of container

Blister strip of 12 lozenges: Carton for 2 blisters in a Poly-Alu pouch.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Unique Pharmaceutical Laboratories

(A Division of J. B. Chemicals & Pharmaceuticals Limited)

8 MARKETING AUTHORISATION NUMBER

06873/07793/REN/2021

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/07/2003

10 DATE OF REVISION OF THE TEXT

26/12/2013