

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dequadin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 0.25 mg dequalinium chloride BP

3 PHARMACEUTICAL FORM

Lozenge

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the local therapy of most of the common infections of the mouth including: Vincents angina, pharyngitis, sore throats, tonsillitis, stomatitis, aphthous ulcers, thrush, glossitis.

4.2 Posology and method of administration

For oral administration.

Adults and children over 10 years: One lozenge to be sucked every 2 to 3 hours, up to a maximum of eight in one day.

Elderly

There is no need for a dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

The label states:

Keep all medicines out of the reach of children. If symptoms persist, consult your doctor.

Warning: Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

4.6 Pregnancy and lactation

The safety of Dequadin during pregnancy and lactation has not been established, but it is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Occasional hypersensitivity reactions and soreness of the tongue are possible.

4.9 Overdose

Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dequalinium chloride is a quaternary ammonium antiseptic active against many gram-positive and gram-negative bacteria, yeasts and fungi.

5.2 Pharmacokinetic properties

Not available.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Icing sugar, citric acid monohydrate, liquid glucose, sodium saccharin, camphor, magnesium stearate, gelatin, sunset yellow, lime flavour, peppermint oil. Purified water not detected in final formulation.

6.2 Incompatibilities

None.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container
PVC/PVDC blister strips sealed with aluminium foil enclosed in a cardboard carton to give packs of 20 or 40 lozenges.

6.6 Special precautions for disposal
None

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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