Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dequadin 0.25 mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 0.25 mg dequalinium chloride

Excipient: Sunset yellow (E110) 0.4 mg per lozenge.
Sucrose 998.925mg per lozenge.
Liquid Glucose 50mg per lozenge.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge.
Round, pale-orange lozenges.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the local therapy of most of the common infections of the mouth and oropharynx 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 dosage reduction in 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 considered 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 quanternary 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

Sucrose
Citric acid monohydrate
Liquid glucose
Saccharin sodium
Racemic camphor
Magnesium stearate
Gelatin
Sunset yellow (E110)
Lime flavour
Peppermint oil

6.2 Incompatibilities

Not applicable.

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 cardboard cartons to give packs of 20 or 40 lozenges.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 0979/036/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 October 1986

Date of last renewal: 26 August 2006

10 DATE OF REVISION OF THE TEXT

February 2009