Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bradosol Plus Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Domiphen Bromide 0.5 mg
Lidocaine Hydrochloride 5.0 mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

A bright green, flat-biconvex cylindrical lozenge.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the management of superficial infections of the mouth and oropharynx.

4.2 Posology and method of adminstration

Adults and Children over 12 years only:
One lozenge to be sucked every 2-3 hours as required
A maximum number of 8 lozenges per day should not be exceeded

Method of administration: Oromucosal use

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.

4.4 Special warnings and special precautions for use

The local anaesthetic may affect swallowing reflexes.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

No information given.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

This product may give rise to allergic reactions, sensitisation may also develop.

4.9 Overdose

No information given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antiseptic/local anaesthetic combination lozenge.

5.2 Pharmacokinetic properties

No information given.

5.3 Preclinical safety data

No information given.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate
Menthol
Eucalyptus oil
Quinoline yellow (E104)
Indigo carmine (E132)
Acesulfame Potassium
Isomalt

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

1 year.

6.4 Special precautions for storage

Do not store above 25°C.
Store in original package.

6.5 Nature and contents of container

PVC/PVDC blister packs.

Pack size: 20, 24 lozenges.
Not all pack sizes may be marketed.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Limited,

Trading as Novartis Consumer Health,

Wimblehurst Road,
Horsham,
West Sussex,
RH12 5AB,
England.

8 MARKETING AUTHORISATION NUMBER

PA 30/37/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd March 1989

Date of last renewal: 3rd March 2004

10 DATE OF REVISION OF THE TEXT

May 2004