

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rinstead Adult Gel 0.106% w/w with Benzocaine 2.0% w/w Oromucosal Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Gel contains 2.0% w/w benzocaine and 0.106% w/w chloroxylenol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal gel.

Clear, light yellow viscous gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of pain in mouth ulcers and aphakia of the oral mucous membranes.

4.2 Posology and method of administration

Adults and Children over 12 years: Apply a small amount to sore area with a clean finger or swab up to 6 times daily.

Children : Not recommended for use in infants or small children.

Route of Administration

Topical application to the inside of the mouth

4.3 Contraindications

Use in patients hypersensitive to the active ingredients.

4.4 Special warnings and precautions for use

Should sensitivity or irritation develop, use should be discontinued immediately.

If symptoms persist for more than 2 weeks, consult your doctor.

Do not exceed the stated dose.

Not for use in infants or small children.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

None stated.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Stomatological preparations, Other agents for local oral treatment, various, ATC code: A01A D11

Benzocaine is a local anaesthetic widely used for topical administration.
Chloroxylenol is a disinfectant of low toxicity, active against streptococci.

5.2 Pharmacokinetic properties

Not relevant to local application for therapeutic purposes.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Clove Oil
Glycerol
Carmellose sodium
Saccharin sodium
Sodium ricinoleate (50%)
Ethanol
Purified Water

6.2 Incompatibilities

None known.

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

10g or 15g Epoxy lacquered aluminium tubes fitted with polyethylene caps, containing 10g or 15g of gel. The tubes are contained in cardboard outer cartons.

Not all pack sizes may be marketed.

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

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1410/078/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 August 1991
Date of last renewal: 08 August 2006

10 DATE OF REVISION OF THE TEXT

April 2015