

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rinstead Sugar Free 0.033% w/w + 0.128% w/w Pastilles.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pastille contains:
Levomenthol 0.033% w/w
Cetylpyridinium Chloride 0.128 % w/w
Excipients: Also includes amaranth (E123) 0.011% w/w and sorbitol (E420) 35.7% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pastille.

A smooth, round, red translucent pastille.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of local irritation of the mouth (e.g. mouth ulcers) or pharynx.

4.2 Posology and method of administration

Adults and children over 12 years:
Allow one pastille to dissolve slowly in the mouth about every two hours.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

None stated.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

No special warnings.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Sensitisation to the product is a possible undesirable effect. There have been very rare reports from clinical trials of hypersensitivity reactions (including oedema of the mouth and face).

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

Systemic effects due to overdosage are most unlikely due to low toxicity of the ingredients. If overdose is suspected, this should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Levomenthol, applied locally in low concentrations, provides a soothing effect.

Cetylpyridinium chloride is an antiseptic, active against a wide spectrum of micro-organisms.

5.2 Pharmacokinetic properties

Levomenthol is excreted in the urine and bile as a glucuronide.

Cetylpyridinium chloride is poorly absorbed and is excreted mainly via the faeces.

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

Tartaric acid
Amaranth (E123)
Rinstead Oils
Sodium ricinoleate
Acesulfame Potassium
Acacia
Silicone antifoam
Sorbitol (E420)
Water (potable)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium foil/clear PVC blister strips contained in a cardboard carton.
Pack sizes of 12, 24, 30, 36 and 48 pastilles.

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

PA1410/077/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 April 1997

Date of last renewal: 04 April 2007

10 DATE OF REVISION OF THE TEXT

April 2015