Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

RBC Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 25 g of paste contains 1.8% w/w of Antazoline hydrochloride, 8% of Calamine, 0.5% of Cetrimide.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cream
A pale pink paste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of allergic skin disorders such as pruritus, urticaria, insect bites and stings, nettle rash, hives, for the relief of itching accompanying chicken pox and shingles, for the relief of sunburn and prickly heat.

4.2 Posology and method of administration

For external use only.
Apply sparingly 3 to 4 times daily for up to 3 days or as directed by the physician.

4.3 Contraindications

Eczema, open wounds, symptoms persisting for more than 2-3 days.
Sensitivity to any constituent.

4.4 Special warnings and precautions for use

If symptoms persist after 2-3 days, consult a doctor.
Discontinue in case of skin sensitivity.
Do not apply to open wounds or eczema.
For external use only.
Keep all medicines away from children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No adverse effects known.

4.7 Effects on ability to drive and use machines

No or negligible effect.

4.8 Undesirable effects

Rare cases of sensitivity have been reported, which subside on application being discontinued.

4.9 Overdose

Not applicable; for external use only.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antazoline is a weak antihistamine with local anaesthetic properties.
Cetrimide is an antiseptic.
Calamine is a mild astringent with mild antiseptic properties, the latter are probably due to the ability of the Zinc ion to precipitate protein.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No data of relevance additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic acid
Cetomacrogol 1000 EW
Light liquid paraffin
Propylene glycol
Glycerol
Camphor
Menthol
Potassium sorbate
Citric acid Monohydrate
Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

25 g aluminium tubes.

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 conditions.

7 MARKETING AUTHORISATION HOLDER

Co-Pharma Limited
Unit 4
Metro Centre
Tolpits Lane
Watford
Hertfordshire
WD1 8SS

8 MARKETING AUTHORISATION NUMBER

PA 894/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 11 August 2001

10 DATE OF REVISION OF THE TEXT

Agust 2001