

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zinc and Castor Oil Cream B.P.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide Ph. Eur. 7.5% w/w.

3 PHARMACEUTICAL FORM

Cutaneous cream

A smooth white to off-white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Acts as a soothing and protective application in eczema and as a protective for slight excoriations and sore areas of the skin. It is a protection against nappy rash in infants.

4.2 Posology and method of administration

4.2.1. Dosage

The cream is applied after washing and drying the affected area. This is repeated at each nappy change in the case of nappy rash.

4.2.2. Administration

Cutaneous (topical) use only.

4.3 Contraindications

Use in persons hypersensitive to any of the ingredients of the preparation.

4.4 Special warnings and precautions for use

For external use only.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions known.

4.6 Pregnancy and lactation

Use in pregnancy and lactation has not been established for this product, however, due to the established nature of the ingredients, no adverse effects are anticipated.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc & Castor Oil Cream B.P. is used as an emollient and astringent skin application.

5.2 Pharmacokinetic properties

Not relevant.

5.3 Preclinical safety data

Zinc Oxide

Skin and eye irritation :

Skin (rabbit) : 500 mg/24H - Mild

Eye (rabbit) : 500mg/24H - Mild

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Castor oil
Cetostearyl alcohol
White beeswax
Arachis oil

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

Polypropylene jars with tamper evident plastic cap.

100g & 500g.

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

None.

7 MARKETING AUTHORISATION HOLDER

Foran Chemicals Ltd.
2 Cherry Orchard Industrial Estate
Ballyfermot
Dublin 10

8 MARKETING AUTHORISATION NUMBER

PA 484/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 1988

Date of last renewal: 01 September 1998

10 DATE OF REVISION OF THE TEXT

September 1998