

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Baby Care Zincastr Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide	7.5% w/w
Castor Oil	4.5% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Emollient and astringent skin application. As a soothing and protective application.

4.2 Posology and method of administration

For children, adults and the elderly:
Smear lightly on the affected areas or massage in gently.
For babies: Wash and carefully dry the skin. Apply to the skin lightly and evenly over the whole napkin area, paying particular attention to the folds of the skin and use at every napkin change.

4.3 Contraindications

Known hypersensitivity to any ingredient.

4.4 Special warnings and precautions for use

For external use only. Do not use on broken skin.

Keep all medicines out of the sight and reach of children.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.”

Zinc and Castor Oil Ointment BP contains Arachis Oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with soya allergy should also avoid Zinc and Castor Oil Ointment BP.

or

Zinc and Castor Oil Cream BP contains Arachis Oil (peanut oil) and should not be applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with soya allergy should also avoid Zinc and Castor Oil Cream BP.

4.5 Interaction with other medicinal products and other forms of interaction

May mask x-ray pictures under certain circumstances.

4.6 Pregnancy and lactation

Acceptable for use in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Rashes due to hypersensitivity may occur and treatment should be withdrawn.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdosage is unlikely. If accidentally ingested treatment should be symptomatic. Oral ingestion of large quantities of castor oil may cause nausea, vomiting, colic and diarrhoea.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D02AB Emollients and Protectives

Zinc oxide has a mild antiseptic action, and is useful for relieving the symptoms of nappy rash and other minor skin irritations.

The formulation as a whole acts to provide a mildly antiseptic water resistant emollient barrier for dry skin conditions and nappy rash.

Castor oil is used externally for its emollient effect.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

None available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin

Anhydrous Lanolin

6.2 Incompatibilities

None known

6.3 Shelf life

60 months in unopened container.

6.4 Special precautions for storage

None

6.5 Nature and contents of container

White plastic jar with screw lid.
In sizes: 50 gm, 85 gm, 100 gm, 225 gm.

6.6 Instructions for use/handling

None.

7 MARKETING AUTHORISATION HOLDER

Bell, Sons & Co (Druggists) Ltd
Gifford House
Slaidburn Crescent
Southport
Merseyside
PR9 9AL

8. MARKETING AUTHORISATION NUMBER

PL 03105/0043

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of grant 12 June 1984

Date of renewal 7 August 1999

10 DATE OF REVISION OF THE TEXT

08/12/2023