

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Zinc and Castor Oil Ointment BP or Zinc and Castor Oil Cream BP.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc oxide 7.5% w/w.

Excipient(s) with known effect
Refined Arachis Oil (30.5% w/w)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For relief of the symptoms of nappy rash and as a protective water resistant cream for dry, chapped skin.

4.2. Posology and method of administration

Topical. Applied directly to the skin.

Recommended doses and dosage schedules.

As required, up to four times daily or at each nappy change. The product is suitable for use by adults, children and the elderly.

4.3. Contraindications

Known hypersensitivity to any of the ingredients listed.

4.4 Special warnings and precautions for use

For external use only.

Keep all medicines out of sight and reach of children.

Instruct patients not to 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

No information is available on the safety of the product when used during pregnancy and lactation.

4.7. Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known.

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 or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

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.

5.2. Pharmacokinetic properties

No information available.

5.3. Preclinical safety data

No data of relevance, which is additional to that included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cetostearyl Alcohol
White Beeswax (E901)
Refined Arachis Oil
Virgin Castor Oil

6.2. Incompatibilities

None known.

6.3 Shelf life

36 months unopened.

6.4. Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

100g: Styrene crystal jar and polypropylene cap.
500g: Polypropylene jar with lid

6.6. Instructions for use, handling and disposal

None.

7 MARKETING AUTHORISATION HOLDER

L.C.M. Ltd
Linthwaite Laboratories
Huddersfield
HD7 5QH
England.

8. MARKETING AUTHORISATION NUMBER

PL 12965/0038

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

27/10/2005

10 DATE OF REVISION OF THE TEXT

24/09/2019