

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zinc & Castor Oil Ointment
Zinc Oxide 7.5% w/w
Castor Oil 50% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide 7.5% w/w and Castor Oil, virgin 50% w/w.

Excipients: contains 2.0% w/w Cetostearyl Alcohol and 30.5% w/w Arachis Oil

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

A white homogeneous ointment with a characteristic odour and a smooth oily texture.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- (a) Zinc & Castor Oil Ointment is used as a topical emollient and astringent skin application.
- (b) It 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

Zinc & Castor Oil Ointment is applied topically and is for external use only.

Recommended Use: As an emollient and protective for topical management of nappy rash, pruritus and other mild irritative rashes.

Apply as required after cleansing the affected area. If symptoms persist consult your doctor.

4.3 Contraindications

Zinc & Castor Oil Ointment is contra-indicated in patients with a known sensitivity to its ingredients.

4.4 Special warnings and precautions for use

Zinc & Castor Oil Ointment contains arachis oil (peanut oil). If you are allergic to peanut or soya, do not use this medicinal product. Zinc & Castor Oil Ointment may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

No adverse effects reported.

4.6 Fertility, pregnancy and lactation

No adverse effects reported.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

None reported.

4.9 Overdose

No special procedures or anti-dote is likely to be necessary. In case of over use, wash off with soap and hot water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Zinc Oxide is widely used as a component of many dusting powders, lotions, ointments, creams and pastes. It has covering and protective properties, gives consistency to topical products and is said to have cooling and slightly astringent properties. It is also widely used as a complete sun block due to its UV reflecting properties.

Castor Oil BP

Castor Oil is used externally for its emollient effect. It is also used as a solvent in some injections and is permitted for use as a solvent in food.

Castor Oil is a soothing application to the conjunctive and allays irritation due to foreign bodies in the eye. Castor Oil is used internally as a purgative, but other agents are now generally preferred.

5.2 Pharmacokinetic properties

Zinc Oxide Powder BP

It is unlikely that any Zinc Oxide is absorbed through the skin. Zinc salts are poorly absorbed from the gastro-intestinal tract. Only a small proportion of dietary zinc is absorbed. Zinc is widely distributed throughout the body and is excreted in the faeces with only traces appearing in the urine.

Castor Oil

Castor Oil contains about 80% of the triglycerides of ricinoleic acid and other fatty acid. Castor Oil is believed not to be absorbed by the skin, mixes with the skin surface lipid consisting of glycerides, free fatty acids, wax esters, squalene and cholesterol.

5.3 Preclinical safety data

No further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Beeswax
Arachis Oil (Peanut Oil)
Cetostearyl Alcohol

6.2 Incompatibilities

Zinc & Castor Oil Ointment can reduce the activity of cream and ointments containing tetracyclines and penicillin.

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

Zinc & Castor Oil Ointment is available in pack sizes of 100g and dispensing packs of 500g. The jars are white polypropylene screw cap containers. The screw caps are also made of polypropylene.

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

Ovelle Limited
Industrial Estate
Coe's Road
Dundalk
Co. Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th October 1992

Date of last renewal: 13th October 2007

10 DATE OF REVISION OF THE TEXT

March 2015