

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zinc 15% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide 15% w/w.

Excipients - Contains wool fat 4.25% w/w and cetostearyl alcohol 4.25% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

A white ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

An astringent and protective combination to protect irritated skin and to soothe minor skin irritations, superficial burns and wounds.

4.2 Posology and method of administration

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

4.3 Contraindications

- (1) Use as treatment of fungal infections.
- (2) Use in patients hypersensitive to any ingredients.
- (3) Use in large surface wounds or burns.

4.4 Special warnings and precautions for use

For external use only.

If there is no improvement or aggravation of the condition occurs consult your doctor.

May cause local skin reaction.

Wool fat and Cetostearyl alcohol may cause local skin reactions (e.g. stinging and contact dermatitis).

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

This preparation may make skin and surfaces slippery

4.5 Interaction with other medicinal products and other forms of interaction

Zinc Oxide is incompatible with benzylpenicillin.

4.6 Fertility, pregnancy and lactation

Zinc Ointment is a monograph of the BP 1993 and as such

- (a) No animal reproduction/fertility study was carried out.
- (b) No study carried out.
- (c) No known reason for not using in fertile, pregnant or lactating women.

4.7 Effects on ability to drive and use machines

Presumed to be safe and unlikely to produce an effect.

4.8 Undesirable effects

None reported.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie e-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code D02AB Zinc products

Zinc oxide is mildly astringent and is used topically as a soothing and protective application in eczema and slight excoriations. Zinc oxide reflects ultra violet radiation and is used in sunscreens.

Zinc oxide is mildly astringent, soothing and protective.

5.2 Pharmacokinetic properties

(a) General characteristics

Zinc Oxide Ph. Eur.

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.

(b) Characteristics in patients

Not applicable.

5.3 Preclinical safety data

Monograph of the BP 1993 and historically in many editions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool Fat

Hard Paraffin
Cetostearyl Alcohol
White Soft Paraffin

6.2 Incompatibilities

Zinc Oxide reacts with fatty acids in oils and fats.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep the container tightly closed.

6.5 Nature and contents of container

100g in 150ml white polypropylene jar with white polypropylene lid.
500g in 650ml white polypropylene jar with white polyethylene lid.

Not all pack sizes may be marketed.

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
Coes Road
Dundalk
Co Louth

8 MARKETING AUTHORISATION NUMBER

PA0206/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 November 1994

Date of last renewal: 10 November 2009

10 DATE OF REVISION OF THE TEXT

November 2017