

Brand Name : ZINC OXIDE OINTMENT USP 20 % W/W		2021
Module 1	Administrative Information and Product Information	
1.5	Product Information	Confidential

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Zinc Oxide Ointment USP 20 % W/W

1.1 (Trade) name of product

Zinc Oxide Ointment USP 20 % W/W

1.2 Strength

Each gram contains: Zinc Oxide Ointment USP 200 mg

1.3 Pharmaceutical Dosage Form

Topical Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Each gram contains: Zinc Oxide Ointment USP 200 mg

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Qty. / Gram
<u>ACTIVE</u>			
Zinc Oxide	USP	20 %	100.000 gm
<u>NON ACTIVE</u>			
Light liquid paraffin	BP	-	75.000 gm
White soft paraffin	BP	-	325.000 gm

USP = United states Pharmacopoeia
BP = British Pharmacopoeia.

3. PHARMACEUTICAL DOSAGE FORM

Topical Ointment

White, homogenous, smooth Ointment free from grittiness.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

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 oxide 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 oxide Ointment 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 zinc oxide may cause nausea, vomiting, colic and diarrhoea.

5. PHARMACOLOGICAL PROPERTIES

Zinc oxide is a mineral ingredient of various pharmacological preparations to treat diaper dermatitis and other skin conditions, to protect the epidermis, and to prevent sunburn.

Zinc oxide is an inorganic compound used in a number of manufacturing processes. It can be found in rubbers, plastics, ceramics, glass, cement, lubricants, paints, ointments, adhesives, sealants, pigments, foods, batteries, ferrites, fire retardants, and first-aid tapes. It occurs naturally as the mineral zincite, but most zinc oxide is produced synthetically. It is also widely used to treat a variety of other skin conditions, in products such as baby powder and barrier creams to treat diaper rashes, calamine cream, anti-dandruff shampoos, and antiseptic ointments.

5.1 Pharmacodynamics properties

Zinc oxide has astringent, soothing and protective properties and is used in topical preparations for eczema, slight excoriations, wounds and hemorrhoids. It also reflects ultraviolet radiation and can be used as a physical sunscreen.

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.

No mutagenicity from Ceftriaxone has been observed.



6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Light liquid paraffin	BP	75.000 gm
White soft paraffin	BP	325.000 gm

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage


Store under normal storage conditions (15°C to 30°C).

Protect from light.


Keep all medicines out of reach of children.

6.5 Nature and Contents of Container

500 gram jar with caps.


ANIL K. PANDEY
DIRECTOR

Date:
Director of the manufacturer
(Signature, Full name, Stamp)


ANIL K. PANDEY
DIRECTOR

Date:
Director of applicant company
(Signature, Full name, Stamp)