	Module 1 Administrative and Product Information
	FRESHBORN
	Zinc Oxide 15.25% w/w Cream

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

Zinc Oxide 15.25% w/w Cream

2. Qualitative and Quantitative Composition

Composition:

Zinc Oxide BP15.25 % w/w

Cream Base.....Q.S.

3. Pharmaceutical Form

Cream.

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.

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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 benzyl penicillin.

4.6 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.

4.9 Overdose

If someone swallows a lot of zinc oxide, give them water or milk right away. Do NOT give water or milk if the person is vomiting or has a decreased level of alertness. If the chemical is on the skin or in the eyes, flush with lots of water for at least 15 minutes.

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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


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

Not known.

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6. Pharmaceutical Particulars

6.1 List of Excipients

Cetostearyl Alcohol, Self-Emulsifying Glyceryl Monostearate, Cetomacrogol Emulsifying Wax, Silicone Oil, White Soft Paraffin, Light Liquid Paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Disodium Edetate, Sodium Acid Phosphate, Sodium Phosphate and Purified Water.

6.2 Incompatibilities

Zinc Oxide reacts with fatty acids in oils and fats.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

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

6.5 Nature and Contents of Container

1 FRESHBABE (30 gm Lamitube) packed in inner carton with a packaging insert.

6.6 Special Precautions for Disposal and Other Handling

Not applicable.

7. Name of Applicant

FRESHBORN INDUSTRIES LIMITED,
45 ASHOGBO STREET,
IDUMOTA,
Lagos State, NIGERIA

MANUFACTURER:

CLAROID PHARMACEUTICALS PVT. LTD
SURVEY NO. 217/P, OPP. GURUKUL ENGLISH MEDIUM SCHOOL KAMOD PIRANA ROAD,
DASKROI, DIST. AHMEDABAD