

Peuraderm
CRÈME

COMPOSITION:

Clotrimazole BP 0,05 % w/w
Menthol 1,00 % w/w
Icthammol BP 0,20 % w/w
Acide borique BP 1,00 % w/w
Oxyde de zinc BP 5,00 % w/w
Base de crème Q.S

NAFDAC Reg. NO.:

POUR USAGE EXTERNE UNIQUEMENT

Conserver à une température not exceeding ne dépassant pas 30°
Protéger de la chaleur et de la lumière directe la lumière direct du soleil
Tenir hors de portée des enfants
Ne pas avaler
Lire attentivement la notice avant utilisation
Eviter le contact avec les yeux
Utiliser selon les directives du



Mfg. Lic. No. :

BATCH NO.:

MFG. DATE:

EXP. DATE:



Peuraderm[®]
ANTIFONGIQUE ET ANTI-DÉMANGEAISONS **CRÈME**

20g



- ▶ Boutons de chaleur
 - ▶ Eczéma
 - ▶ Pied d'athlète
 - ▶ Taches
- & autres irritations cutanées

COMPOSITION:

Clotrimazole BP 0.05% w/w
Menthol 1.00% w/w
Icthammol BP 0.20% w/w
Boric Acid BP 1.00% w/w
Zinc Oxide BP 5.00% w/w
Cream base Q.S

NAFDAC Reg. NO.:

FOR EXTERNAL USE ONLY

Store at a temperature not exceeding 30°
Protect from heat and direct sunlight.
Keep out of reach of children.
Do not swallow.
read package insert carefully before use
Avoid contact with the eyes.
Use as directed by the physician.

Manufactured in India by
Claroid Pharmaceuticals Pvt Ltd
Survey No. 217/P, Opposite Gurukul English Medium School, Kamod Pirana Road,
Ta-Daskroi, Dist-Ahmedabad-382425, Gujarat, India.

Exported by:
Welcare Lifesciences
991/1/B-3, G.I.D.C, Opp. Gayatri ice factory, Nr. Makarpura bus depot, Makarpura,
Vadodara-390010, Gujarat, India.

VENCHURA[®]
Pharmaceuticals Limited 5, Mercy Eneli Street, Surulere, Lagos State.

- ▶ Heat rash
- ▶ Eczema
- ▶ Athlete's foot
- ▶ Blemishes
- ▶ & other skin irritations



Peuraderm[®]
ANTIFUNGAL & ANTI-ITCH
CREAM



20g

Peuraderm
CREAM

**PEURADERM CREAM
CLOTRIMAZOLE, MENTHOL, ICHTHAMMOL, BORIC ACID & ZINC OXIDE
CREAM**

INDIA

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of Medicinal Product

PEURADERM CREAM

**CLOTRIMAZOLE, MENTHOL, ICHTHAMMOL, BORIC ACID & ZINC OXIDE
CREAM**

2. Qualitative and Quantitative Composition

2.1. Qualitative declaration:

CLOTRIMAZOLE BP

MENTHOL BP

ICHTHAMMOL BP

BORIC ACID BP

ZINC OXIDE BP

2.2. Quantitative declaration:

Composition of the Drug product:

Clotrimazole BP	0.5% w/w
Menthol BP	1.0 % w/w
Icthammol BP	0.20% w/w
Boric acid BP	1.00% w/w
Zinc oxide BP	5.00% w/w
Cream Base	Q.S.

Qualitative & Quantitative Composition Formula:

Batch Size: 300 KG

Sr. No	Name of Ingredients	Spec.	% content % w/w	Std. Qty per batch (in kg)
Oil Phase				

CLAROID PHARMACEUTICALS PVT. LTD.
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01	Clotrimazole	BP	0.50	1.50
02	Menthol	BP	1.00	3.000
03	Ichthammol	BP	0.20	0.60
04	Boric acid	BP	1.00	3.00
05	Zinc oxide	BP	5.00	15.00
06	Chlorocresol	BP	0.10	0.30
07	Benzyl Alcohol	BP	0.50	1.50
08	Cetostearyl Alcohol	USP	4.00	12.00
09	Self-Emulsifying Glyceryl Monostearate	BP	4.00	12.000
10	Cetomacrogol Emulsifying Wax	BP	2.00	6.000
11	Silicone Oil	IHS	1.00	3.000
12	White Soft Paraffin	BP	15.00	45.000
13	Light Liquid Paraffin	BP	6.00	18.000
14	Methyl Paraben	BP	0.16	0.480
15	Propyl Paraben	BP	0.08	0.240
16	Propylene Glycol	BP	7.00	21.000
Manufacturing Vessel				
17	Disodium Edetate	BP	0.10	0.300
18	Sodium Acid Phosphate	BP	0.10	0.300
19	Sodium Phosphate	BP	0.10	0.300
20	Rose Flavour	IHS	0.17	0.510
21	Purified Water	IHS	51.99	159.089 (155.970 +2%)
Section: Ointment		Total Batch Quantity: 300.000 kg		
Note: 2% Extra Purified Water added to compensate loss during manufacturing.				

3. Pharmaceutical form

CLAROID PHARMACEUTICALS PVT. LTD.
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A White to off white gelatinous homogenous mass.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of skin infections due to dermatophytes (e.g. trycophyton species), yeasts (e.g. candida species), moulds and other fungi. These include ringworm (tinea) infections, paronychia, pityriasis versicolor, erythrasma and intertrigo.

4.2 Posology and method of administration

For cutaneous administration.

Posology

Apply the cream twice daily to the affected skin. Treatment should be prolonged for 10 days after all skin diseases have disappeared to prevent relapse or as directed by the physician.

4.3 Contraindications

Known hypersensitivity to any of the components.

4.4 Special warnings and precautions for use

Do not use on the eyes or face. Do not use for other bites or stings or for other skin conditions.

Do not swallow or place in Nostrils. Keep away from Eyes.

4.5 Interaction with other medicinal products and other forms of interaction

There are no interactions with medicines

4.6 Fertility, pregnancy and lactation

Pregnancy

This product should not be used in pregnancy without medical advice.

Lactation

Contraindicated in breast feeding mothers.

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4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Immune system disorders- Allergic reaction (syncope, hypotension, dyspnoea, urticaria).

Skin and subcutaneous tissue disorder- Blisters, discomfort/pain, oedema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

4.9 Overdose

In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Clotrimazole - antifungal medications called imidazoles

(ATC code : D01AC01)

Menthol- topical analgesic.

Ichthammol - local therapeutic agents with anti-inflammatory, bactericidal, and fungicidal properties.

(ATC code : D10BX01)

Boric Acid – astringent properties.

(ATC code : S02AA03)

Zinc Oxide: skin protection and as a UV absorber

Peuraderm cream is a combination of Clotrimazole, Menthol, Ichthammol, Zinc Oxide and Boric Acid where Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. The mode of action of Peuraderm cream is fungistatic or fungicidal depending on the concentration of Clotrimazole at the site of infection

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5.2 Pharmacokinetic properties

Peuraderm cream is minimally absorbed from the intact or inflamed skin into the human blood circulation

5.3 Preclinical safety data

There is no pre-clinical safety data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol	BP
Benzyl Alcohol	BP
Cetostearyl Alcohol	USP
Self-Emulsifying Glyceryl Monostearate	BP
Cetomacrogol Emulsifying Wax	BP
Silicone Oil	IHS
White Soft Paraffin	BP
Light Liquid Paraffin	BP
Methyl Paraben	BP
Propyl Paraben	BP
Propylene Glycol	BP
Disodium Edetate	BP
Sodium Acid Phosphate	BP
Sodium Phosphate	BP
Rose Flavour	IHS
Purified Water	IHS

6.2 Incompatibilities:

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Not applicable.

6.3 Shelf-life: 36 months

6.4 Special precautions for storage:

Store at a temperature not exceeding 30 °C, Protect from heat and direct sunlight.

Keep out of reach of children.

6.5 Nature and contents of container:

PEURADERM CREAM: 20 GM Tube packed in a carton with insert.

6.6 Special precautions for disposal and other handling

No special instructions for disposal.

Do not swallow.

Avoid contact with eyes.

7. Marketing Authorization Holder:

VENCHURA PHARMACEUTICALS LIMITED.,

5, Mercy Eneli Street, Surulere,

Lagos, Nigeria.

8. Marketing Authorization Number (s):

Product license / registration Number (s)

9. Manufacturer Name:

Claroid Pharmaceuticals Pvt. Ltd.

Survey no. 217/p, opp. Gurukul English medium school,

Kamod pirana road,tal.daskroi,

Dist.- ahmedabad – 382425,

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10. Date of first authorization/renewal of the authorization:

11. Date of revision of the text:

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