

COMPOSITION:

Clotrimazole BP 0.05% w/w
Ichthammol BP 0.20% w/w
Base de crème Q.S

POUR USAGE EXTERNE UNIQUEMENT

Conservé 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:

NAFDAC Reg. NO.:

**Baby
Peuraderm
Cream**



**Baby
Peuraderm[®]
Cream**

Diaper rash, Heat rash & other skin irritations



20g

COMPOSITION:

Clotrimazole BP 0.05% w/w
Ichthammol BP 0.20% w/w
Cream base Q.S

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.

NAFDAC Reg. NO.:



**Bébé
Peuraderm[®]
Crème**



Eruption cutanée, éruption cutanée et autres irritations cutanées

20g

**Baby
Peuraderm
Cream**

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of Medicinal Product

BABY PEURADERM CREAM

CLOTRIMAZOLE & ICHTHAMMOL CREAM

2. Qualitative and Quantitative Composition

2.1. Qualitative declaration:

CLOTRIMAZOLE BP

ICHTHAMMOL BP

2.2. Quantitative declaration:

Composition of the Drug product:

Each gram contains:

Clotrimazole BP 0.05% w/w

Ichthammol BP 0.20% 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				
01	Clotrimazole	BP	0.05	0.15
02	Ichthammol	BP	0.20	0.60
03	Chlorocresol	BP	0.10	0.30
04	Benzyl Alcohol	BP	0.50	1.50
05	Cetostearyl Alcohol	USP	4.00	12.00
06	Self-Emulsifying Glyceryl	BP	4.00	12.000

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**BABY PEURADERM CREAM
CLOTRIMAZOLE & ICHTHAMMOL CREAM****INDIA**

	Monostearate			
07	Cetomacrogol Emulsifying Wax	BP	2.00	6.000
08	Silicone Oil	IHS	1.00	3.000
09	White Soft Paraffin	BP	15.00	45.000
10	Light Liquid Paraffin	BP	6.00	18.000
11	Methyl Paraben	BP	0.16	0.480
12	Propyl Paraben	BP	0.08	0.240
13	Propylene Glycol	BP	7.00	21.000
Manufacturing Vessel				
14	Disodium Edetate	BP	0.10	0.300
15	Sodium Acid Phosphate	BP	0.10	0.300
16	Sodium Phosphate	BP	0.10	0.300
17	Rose Flavour	IHS	0.17	0.50
18	Purified Water	IHS	59.44	181.89 (178.33 +2%)
Section: Ointment		Total Batch Quantity: 300.000 kg		
Note: 2% Extra Purified Water added to compensate loss during manufacturing.				

3. Pharmaceutical form

A White to off white gelatinous homogenous mass.

4. Clinical particulars**4.1 Therapeutic indications**

Used in diaper rashes, heat rash & other skin irritations

Diaper rash is the most common skin problem in babies. Wetness and friction are the most frequent causes of this rash and seem unavoidable. To protect baby's delicate skin, diaper rash creams are valuable. These creams can both prevent and cure diaper rash when used correctly.

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4.2 Posology and method of administration

For cutaneous administration.

Diaper creams are used to prevent or cure a diaper rash. Correct use is important to get the most benefit:

- Always apply the diaper cream to dry skin. It'll keep moisture off the skin. If you apply the cream to wet skin, it'll trap the moisture on your baby's skin.
- Don't rub the diaper cream into the skin. Gently spread a thick layer.
- Don't wash it off at every diaper change. Once a day at night is enough.

4.3 Contraindications

- History of sensitivity/hypersensitivity reactions 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.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

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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)

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

(ATC code : D10BX01)

Baby Peuraderm cream is a combination of Clotrimazole & Ichthammol, 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 Baby Peuraderm cream is fungistatic or fungicidal depending on the concentration of Clotrimazole at the site of infection.

5.2 Pharmacokinetic properties

Baby 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:

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.

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6.5 Nature and contents of container:

BABY 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,

Gujarat, India.

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

11. Date of revision of the text:

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