
COMPOSITION:
Un gramme de crème contient;
10mg Hydrocortisone BP
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:
A1234567890A
Hydrocortisone
Crème 1%
VENCHURA®
Hydrocortisone
Crème 1%
15g
NAFDAC Reg. NO.:
COMPOSITION:
One gram of cream contains;
10mg Hydrocortisone B.P
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.
for VENCHURA® Pharmaceuticals Limited
5, Mercy Eneli Street, Surulere, Lagos State.
15g
NAFDAC Reg. NO.:
Hydrocortisone
Cream 1%
VENCHURA®
Hydrocortisone
Cream 1%

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of Medicinal Product

HYDROCORTISONE CREAM 1%

HYDROCORTISONE CREAM 1%

2. Qualitative and Quantitative Composition

2.1. Qualitative declaration:

Hydrocortisone BP

2.2. Quantitative declaration:

Composition of the Drug product:

Each gram contains:

Hydrocortisone BP 10 mg

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	Hydrocortisone	BP	1.00	3.000
02	Cetostearyl Alcohol	BP	4.00	12.000
03	Self-Emulsifying Glyceryl Monostearate	BP	4.00	12.000
04	Cetomacrogol Emulsifying Wax	BP	2.00	6.000
05	Silicone Oil	IHS	1.00	3.000
06	White Soft Paraffin	BP	15.33	46.000

07	Light Liquid Paraffin	BP	6.67	20.000
08	Methyl Paraben	BP	0.16	0.480
09	Propyl Paraben	BP	0.08	0.240
10	Propylene Glycol	BP	8.00	24.000
Manufacturing Vessel				
11	Disodium Edetate	BP	0.10	0.300
12	Sodium Acid Phosphate	BP	0.10	0.300
13	Sodium Phosphate	BP	0.10	0.300
14	Purified Water	IHS	57.46	175.828 (172.380 +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

Hydrocortisone is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

A thin film should be applied to the affected area three to four times daily. Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations.

4.3 Contraindications

Hydrocortisone is contraindicated in patients with a history of hypersensitivity to the product or any of its constituent ingredients, patients with tuberculosis or fungal infection and/or herpes infections of the eyes, lips, or genitals.

4.4 Special warnings and precautions for use

Although extensive use of hydrocortisone has not revealed evidence that enough hydrocortisone is absorbed to have systemic effects, greater absorption because of misuse or individual variability or unusual sensitivity could lead, at least theoretically, to a systemic effect. Patients are advised to contact their physician if the condition under treatment worsens or if symptoms persist for more than seven days or if symptoms clear and occur again within a few days. Hydrocortisone is not recommended for use in children under two years of age. Hydrocortisone should not be used for external feminine itching if a vaginal discharge is present. It is not to be used for external anal itching if bleeding is present. Contact with the eyes should be avoided. Hydrocortisone should not be used under waterproof dressings unless advised to do so by a physician. Hydrocortisone should not be used to treat acne.

If the product is applied with the fingertips, hands should be washed afterwards. Visual disturbance Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids

4.5 Interaction with other medicinal products and other forms of interaction

There are currently no known drug interactions associated with the topical application of hydrocortisone.

4.6 Use during pregnancy and lactation

Pregnancy

The safety of this medicinal product for use during human pregnancy or during lactation has not been established.

Breast-feeding

Hydrocortisone should only be used during pregnancy or lactation if recommended by a physician.

Fertility

No data on fertility available

4.7 Effects on ability to drive and use machines

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

4.8 Undesirable effects

The safety profile of topically applied hydrocortisone preparations has been established through over 40 years of marketing experience. Topically applied hydrocortisone generally does not produce systemic effects due to minimal absorption. Absorption increases in the presence of skin inflammation or with the use of occlusive agents. Certain local effects such as skin atrophy may arise with prolonged use because of the antimitotic/antisynthetic effect of hydrocortisone on cells. Clinically detectable atrophy rarely occurs with hydrocortisone in concentrations available without prescription (0.5%, 1.0%).

General disorders and administration site conditions Rebound effect – see Section 4.2 Dose and method of administration.

4.9 Overdose

There is no specific overdosage syndrome associated with the use of topical hydrocortisone. No specific antidote is available. Treatment of acute oral overdose consists of dilution with fluids.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroid

ATC group: D07AA02

When applied topically, hydrocortisone diffuses across cell membranes to form complexes with specific cytoplasmic receptors. These complexes enter the cell nucleus, bind to DNA, and stimulate transcription of messenger RNA and subsequent protein synthesis of enzymes responsible for antiinflammatory effects, including inhibition of oedema, fibrin deposition,

capillary dilation, and movements of phagocytes. Later stages of inflammation such as capillary production, collagen deposition, and keloid formation are also inhibited.

At a concentration of 1%, topically applied hydrocortisone has been found to bring about both subjective and objective improvements, usually within one week and often as soon as 24 to 48 hours after initiation of therapy. Systemic effects from prolonged external application of large amounts of hydrocortisone to wide areas of damaged skin have been minimal. Adrenal axis suppression has not been observed.

5.2 Pharmacokinetic properties

Following topical application, hydrocortisone diffuses through the skin by both transfollicular and transepidermal routes. Absorption varies according to anatomic site of application and ranges from 1% (forearm skin) to 26-29% (mucous membranes). Factors influencing penetration include concentration, vehicle, anatomic site, age, condition of the skin, and occlusion. The plasma level of hydrocortisone falls to 50% of its initial concentration in 90 minutes; the biological half-life of hydrocortisone is 8 to 12 hours. Biotransformation takes place primarily in the skin, and for any amount absorbed systematically, in the liver. 0.2% to 1.0% of hydrocortisone appeared in the urine over 10 days after topical application of C-14 radiolabelled hydrocortisone to normal skin.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the prescriber which are additional to those included in other sections.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl Alcohol	BP
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
Purified Water	IHS

6.2 Incompatibilities:

In the absence of compatibility studies, this medicine must not be mixed with other medicines.

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:

HYDROCORTISONE CREAM 1%: 15 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:
