

1.1 Name of the medicinal product:
HYDROCORTISONE CREAM BP 1% W/W
1.2 Qualitative and quantitative composition:

Composition:

- Hydrocortisone BP.....1% W/W
- Cream Base (- QS)

Sr. No.	Ingredients	Specifi- cation	Label Claim w/w	Over- ages added (In %)	Quantity in % w/w	Reason for Function
1.	Hydrocortisone	BP	1.00%	NA	1.00%	Medicament
2.	Cetostearyl Alcohol	BP	NA	NA	8.00%	Thickening Agent, Stabilizing Agent
3.	Cetomacrogol 1000	IH	NA	NA	2.00%	Emollient
4.	Light liquid paraffin	BP	NA	NA	10.00%	Emollient
5.	Hard paraffin Wax	BP	NA	NA	4.20%	Emollient
6.	Micro Crystalline Wax	IH	NA	NA	1.00%	Thickening agent
7.	Propylene Glycol	BP	NA	NA	3.00%	Solvent
8.	Butylated Hydroxytoluene	BP	NA	NA	0.05%	Preservative
9.	Chlorocresol	BP	NA	NA	0.10%	Preservative
10.	Purified Water	BP	NA	NA	70.65%	Vehicle

1.3 Pharmaceutical form: Cream

Description: White coloured cream

1.4 Clinical Particulars
4.1 Therapeutic indications

HYDROCORTISONE CREAM BP 1% W/W is a mild topical (applied to the skin) corticosteroid, or 'steroid' Hydrocortisone Cream is used for the relief of mild inflammatory skin disorders including:

- mild to moderate eczema
- irritant contact dermatitis or allergic contact dermatitis
- insect bite reactions

4.2 Posology and method of administration
Route: Topical

Posology

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you purchased this product without a prescription, follow these directions closely.

- Use the spike in the top of the cap to make a hole through the seal of the tube.
- Wash your hands before and after applying Hydrocortisone Cream but if applying to the hands do not wash after application.
- If symptoms persist after 7 days, consult your doctor.

-Adults (including the elderly) and children over 10 years old

Apply sufficient cream once or twice a day to thinly cover the affected area and gently rub into the skin until it disappears. Use the cream for a maximum period of one week.

- Children under 10 years

Do not use in children under 10 years without speaking to your doctor first.

4.3 Contraindications

HYDROCORTISONE CREAM BP 1% W/W is contraindicated

- If you are allergic (hypersensitive) to hydrocortisone or any of the other ingredients of this medicine
- If you are going to apply the cream to your face, eyes or ano-genital region, or to broken or infected skin (including cold sores, acne, athlete's foot or chickenpox).
- If you are going to apply the cream under occlusive dressing.

4.4 Special warnings and precautions for use

Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advice is recommended in these cases or other treatment options should be considered.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and Lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

4.7 Effects on ability to drive and use machines

Hydrocortisone Cream is not expected to affect your ability to drive or operate machinery.

4.8 Undesirable effects

Like all medicines, Hydrocortisone Cream can cause side effects, although not everybody gets them. Most patients using Hydrocortisone Cream will have no problems when used in the correct amount for the prescribed time. If the following happens, stop using the cream and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives). This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

- blurred vision. This side effect has been reported, but the frequency for it to occur is not known.

If your condition becomes worse during treatment, you may have an allergy to one of the ingredients of the cream or an infection. Stop using Hydrocortisone Cream and tell your doctor as soon as possible.

Use of this cream may cause stretch marks on the skin

4.9 Overdose

No special procedures or antidote are likely to be necessary

Topical overdosage may occur where large amounts are applied, or where smaller amounts are applied in occlusive conditions. Overdose ultimately leads to adrenocortical suppression. Treatment is by gradual reduction of the amounts used. The side effects of overuse i.e. skin atrophy, striae etc. may not be reversed.

5 Pharmacological properties**5.1 Pharmacodynamic properties**

Pharmacotherapeutic Group: Corticosteroids, dermatological preparations; corticosteroids, weak (group I); ATC Code: D07AA02

Hydrocortisone, as a mild topical corticosteroid, is used in the treatment of many skin conditions such as eczema, atopic dermatitis, contact dermatitis, seborrhoeic dermatitis and some forms of psoriasis. When administered by topical application, particularly under an occlusive dressing or when the skin is broken, sufficient corticosteroid may be absorbed to give systemic effects.

5.2 Pharmacokinetic properties

The literature states that absorption does occur through the skin, particularly denuded skin. This absorption is not usually of clinical significance as hydrocortisone topically has only rarely been associated with side effects resulting from pituitary-adrenal suppression.

Topically applied steroids may be absorbed to a significant extent if applied to broken skin, to very large areas, or under occlusive dressings.

If systemic absorption occurs, hydrocortisone is extensively bound to plasma proteins, mainly to globulin and less so to albumin. Corticosteroids are metabolised mainly in the liver but also in the kidney, and are excreted in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6 Pharmaceutical particulars**6.1 List of excipients**

Cetostearyl Alcohol, Cetomacrogol 1000, Light liquid paraffin, Hard paraffin Wax, Micro Crystalline Wax, Propylene Glycol, Butylated Hydroxytoluene, Chlorocresol, Purified Water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

- Store at a temperature below 30° C.
- Do not freeze, Protect from direct sunlight.
- Keep all medicines out of the reach of children.
- Avoid contact with eyes.
- Keep the tube tightly close after use.

6.5 Nature and contents of container

Primary packing: 20 gm of cream filled in lami tube.

Secondary packing: Such one lami tube is packed in a carton along with leaflet.

Tertiary packing: 10 Cartons are packed in a shrink. Such 50 shrinks are packed in 5 ply shipper. Shippers to be sealed with BOPP tape.

6.6 Special precautions for disposal and other handling

None

7 Applicant / Manufacturer**Applicant**

Applicant name and address	M/s. PRIYA PHARMACEUTICAL NIG. LTD. No. C-1, Airport Road, 2F, Kano State, Nigeria.
Contact person's phone number	
Contact person's email	

Manufacturer

Manufacturer name and address	M/s. ASTAMED HEALTHCARE (I) PVT. LTD. Plot No. 2 & 3, Phase II, Genesis Ind. Complex, Kolgaon, Dist. Thane, Tal. Palghar, 401404 Maharashtra State, India
Contact person's phone number	+91 9920633632/ +91 9967364363
Contact person's email	nayan.thakkar@astamed.com