

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name

CORTISONE CREAM 1%

1.2 International Non-Proprietary Name

HYDROCORTISONE CREAM 1%

1.3 Strength

1% w/w

1.4 Pharmaceutical Dosage Form

Topical semi-solid

2. Quality and Quantitative Composition:

No.	Name of Ingredient	% w/w	Function	Reference monograph
<u>Active ingredient</u>				
1	Hydrocortisone	1.00	Active ingredient	BP

Kindly refer to 6.1 for the list of excipients.

3. Pharmaceutical Form

White, opaque cream.

4. Clinical Particulars

4.1 Therapeutic Indications

For relief or treatment of:

- Minor skin irritation, itching, and rashes due to eczema, insect bites, poison ivy, oak, or sumac dermatitis, detergents, cosmetics and jewellery.
- Anogenital pruritus

4.2 Contraindications

- Excessive or prolonged usage in pregnancy is not recommended.
- Avoid contact with eyes.
- It should not be applied to ulcers of the leg.

4.3 Posology and Method of Administration

Apply sparingly to the affected area.

Adults : Three or four times a day.

Children : One or two times a day.

4.4 Special Warning and Precautions for Use

- Caution in patients with infection at treatment site, and tuberculosis of the skin.
- Pediatric therapy continuing for longer than 2 weeks should be evaluated carefully by the physician.
- Do not bandage or otherwise wrap the treated skin area unless directed to do so by physician.
- Safety for use in lactation has not been established.

4.5 Drug Interaction

Not applicable

4.6 Pregnancy and lactation

None known

4.7 Effects on ability to drive and use machine

None known

4.8 Undesirable effects

Increase liability to infection; prolonged use include moon face, glaucoma, thinning of skin with easy bruising, increase in hair growth, loss of hair, reddish purple lines on arms, legs, trunk, or groin.

Note: It has fewer side-effects on the skin than the more potent topical corticosteroids.

4.9 Overdose

Clinical features:

Atrophic changes in the skin, secondary infections, burning, itching, irritation, dryness, folliculitis, hypertrichosis, acne, and pigmentation.

Treatment for overdosage:

Treat overdosage by symptomatic measures, where possible the dosage being reduced or the drug slowly withdrawn.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

The anti-inflammatory effect of topical application of hydrocortisone, a less potent corticosteroid, is due to its ability to diffuse across cell membranes and subsequently enters the cell nucleus. It then binds with DNA, and stimulates transcription of messenger RNA resulting in protein synthesis of various enzymes.

5.2 Pharmacokinetic Properties

It is absorbed percutaneously, particularly in denuded areas. Occlusion or use over extensive areas increases topical absorption.

5.3 Preclinical Safety Data

None known

6. Pharmaceutical Particulars

6.1 List of Excipients

Liquid Paraffin
Chlorocresol
Polyethylene Glycol 4000
Cetomacrogol Emulsifying Wax
White Soft Paraffin (Vaseline)
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Store below 30°C. Protect from freezing.

6.5 Nature and Contents of Container

Descriptions of each packaging material for Cortisone Cream 1% is as below:

Primary Packaging Components

Name of Packing Material : Collapsible Aluminium Tube

Package size : 15g per tube

Material of Construction : Body – 99.7% Aluminium purity
Internal lacquered – Epoxy Phenolic
External lacquered – Polyester Enamel
Cap – High Density Polyethylene

Specification : Cap – White screw cap
Finishing (Body) – Internally lacquered, external
preprinted and fitted with caps as per approved
design
Diameter – 18.05 mm – 19.95 mm
Length – 96.9 mm – 107.1 mm

Secondary Packaging Components
Cortisone Cream 1% (15 g) unit box

- 7. Marketing Authorization Holder**
Name : Hovid Bhd.
Address : 121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30100 Ipoh, Perak, Malaysia.
- 8. Manufacturer and Manufacturing Site**
Name : Hovid Bhd.
Address : Lot 56442, 7 ½ Miles, Jalan Ipoh/Chemor,
30010 Chemor, Perak, Malaysia.
- 9. Date of First Authorization / Renewal of the Authorization**
NIL
- 10. Date of Revision of Text**
April 2023