
ATONIDE-H CREAM

1. Generic Name

Hydrocortisone Acetate Cream I.P.

2. Qualitative and quantitative Composition:

Composition:

Hydrocortisone Acetate I.P.1% w/w

Cream Base..... q.s.

The List of excipients used are Butylated Hydroxyl Toluene, Ceto Stearyl Alcohol, Cetomacrogol Emulsifying Wax, Di Sodium EDTA, Light Liquid Paraffin, Mono Sodium Phosphate Di Hydrate, Para Chloro Meta Cresol, Propylene Glycol and White Petroleum Jelly.

3. Dosage form and strength

Dosage form: Cream

Strength: Hydrocortisone Acetate 1% w/w

4. Clinical particulars

4.1. Therapeutic indication

It is indicated for the relief of the inflammatory and pruritic manifestations dermatoses, redness and scaling.

4.2. Posology and method of administration

Posology

Apply Atonide-H Cream to the affected area 2-3 times daily.

Method of administration

For topical application.

4.3. Contraindications

Topical Corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

4.4. Special warnings and precautions for use

Systemic absorption of Atonide-H Cream can produce reversible Hypothalamic-Pituitary Adrenal (HPA) axis suppression with the potential for Glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, Hyperglycemia, and Glucosuria can also be produced in some patients by systemic absorption of Topical Corticosteroids while on treatment.

The treated skin areas should not be bandaged, covered, or wrapped so as to be occluded.

4.5. Drugs interactions

Particular caution should be exercised in using preparations containing Prednisone, Cyclosporine.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Atonide-H Cream should not be used extensively on pregnant patients in large amounts, or for prolonged periods of time. Caution should be exercised when Cream is applied to a nursing mother.

4.7. Effects on ability to drive and use machines

Not Known.

4.8. Undesirable effects

These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, Folliculitis, Hypertrichosis, Acneiform Eruptions, Hypopigmentation, Perioral Dermatitis, and Allergic Contact Dermatitis, maceration of the skin, secondary infection, Skin Atrophy, Striae and Miliaria.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com or at email: pv@torrentpharma.com or call on 1800-120-3001.

4.9. Overdose

Not applicable.

5. Pharmacological properties

5.1. Mechanism of Action

An adrenocortical steroid that inhibits accumulation of inflammatory cells at inflammation sites, phagocytosis, lysosomal enzyme release and synthesis, and release of mediators of inflammation.

5.2. Pharmacodynamic properties

The mechanism of anti-inflammatory activity of the Topical Corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the Topical Corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

5.3. Pharmacokinetic properties

Hydrocortisone can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of Topical Corticosteroids.

Once absorbed through the skin, Topical Corticosteroids are handled through pharmacokinetic pathways similar to systemically administered Corticosteroids. Hydrocortisone bound to plasma proteins in varying degrees. Hydrocortisone is metabolized primarily in the Liver and then excreted by the Kidneys. Hydrocortisone and their metabolites are excreted into the bile.

6. Nonclinical properties

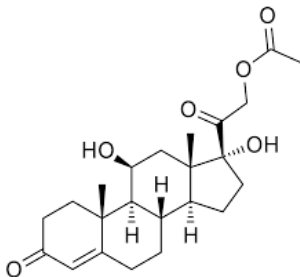
6.1. Animal Toxicology or Pharmacology

Not available.

7. Description

Hydrocortisone Acetate

Hydrocortisone Acetate is 11 β , 17 α -dihydroxy- 3,20- dioxopregn-4-en-21 acetate. The empirical formula is C₂₃H₃₂O₆ and its molecular weight is 404.5 g/mol. The chemical structural formula is:



ATONIDE-H CREAM:

Hydrocortisone Acetate Cream are White, homogenous soft mass cream. The List of excipients used are Butylated Hydroxyl Toluene, Ceto Stearyl Alcohol, Cetomacrogol Emulsifying Wax, Di Sodium EDTA, Light Liquid Paraffin, Mono Sodium Phosphate Di Hydrate, Para Chloro Meta Cresol, Propylene Glycol and White Petroleum Jelly.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable

8.2. Shelf-life

Do not use later than date of expiry.

8.3. Packaging information

ATONIDE-H CREAM is available in pack of 20 gm.

8.4. Storage and handing instructions

Do not store above 30°C. Store protected from light. Do not freeze.

Keep out of reach of Children.

Replace the cap tightly closed after use.

For External use only.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illness
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

10. Details of manufacturer

Yash Pharma Laboratories Pvt. Ltd.
Khasra No. 19-M, Village: Raipur,
Pargana: Bhagwanpur,
Tehsil: Roorkee Distt.: Haridwar,
Uttarakhand – 247661, India.

11. Details of permission or licence number with date

Mfg. Licence. No.: 41/UA/SC/P-2016 Issued on 01.07.2025

12. Date of revision

MAY 2026

MARKETED BY

TORRENT
PHARMA

TORRENT PHARMACEUTICALS LTD.

IN/ATONIDE-H CREAM 1%/MAY-2026/02/PI