
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 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

Dosage Strength: Hydrocortisone Acetate 1% w/w

4. Clinical particulars

4.1 Therapeutic indication

Indication is not available in DCGI list

4.2 Posology and method of administration

Posology

As directed by the Physician

Method of administration

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

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 population (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 suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.

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

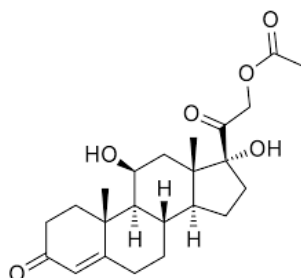
6.1 Animal Toxicology or Pharmacology

NA

7. Description

Hydrocortisone Acetate

Hydrocortisone Acetate is 11 β , 17 α -dihydroxy- 3,20- dioxopregn-4-en-21 acetate. The empirical formula is $C_{23}H_{32}O_6$ 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 filled in printed lami tube. The 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, White Petroleum Jelly.

8. Pharmaceutical particulars

8.1 Incompatibilities

N/A

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 protecting from light. Do not freeze.

Keep out of reach of Children.

Replace the cap tightly closed after use.

9. Patient Counselling Information

Package leaflet: information for the patient

ATONIDE-H CREAM

(Hydrocortisone Acetate Cream I.P.)

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1. What **ATONIDE-H CREAM** is and what it is used for?

9.2. What you need to know before you take **ATONIDE-H CREAM**?

9.3. How to apply **ATONIDE-H CREAM**?

9.4. Possible side effects

9.5. How to store **ATONIDE-H CREAM**?

9.6. Contents of the pack and other information

9.1 What ATONIDE-H CREAM is and what it is used for?

ATONIDE-H CREAM is contains Hydrocortisone Acetate

What you need to know before you take ATONIDE-H CREAM?

For Topical administration.

9.2 What you need to know before you take ATONIDE-H CREAM?

Warnings and precautions

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.

Interactions with other medicines

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

Pregnancy, breast-feeding and fertility

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.

Driving and using machines

Not Known.

9.3 How to Apply ATONIDE-H CREAM

Apply Atonide-H Cream to the affected area 2-3 times daily or as directed by the Physician.

For Topical administration.

9.4 Possible side 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 side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

https://www.torrentpharma.com/index.php/site/info/adverse_event_reporting

By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store ATONIDE-H CREAM

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

9.6 Contents of the pack and other information

ATONIDE-H CREAM contains Hydrocortisone Acetate as active ingredients.

The 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, White Petroleum Jelly.

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

10 Details of manufacturer

Yash Pharma Laboratories Pvt. Ltd.,
Khasra No. 19-M,
Village: Raipur, Pargana: Bhagwanpur,
Tehsil: Roorkee Distt.: Haridwar,
Uttarakhand – 247 661, India.

11 Details of permission or license number with date

Mfg. Licence. No.: 43/UA/LL/SC/P-2016 Issued on. 26.05.2016

12 Date of revision

Not applicable

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

IN/ATONIDE-H CREAM 1%/NOV-23/01/PI