

HYDROCORTISONE ACETATE- hydrocortisone acetate cream
Bentlin Products LLC

Drug Facts

Active Ingredient

Hydrocortisone acetate USP 1.0% w/w

Purpose

Anti-itch

Uses:

For temporary relief of itching associated with minor skin irritation, inflammation and rashes due to:

- Atopic eczema
- Contact dermatitis from soaps, detergents or cosmetics
- Seborrheic dermatitis
- Psoriasis

Other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- For the treatment of diaper rash
- On children under the age of 2 except under the supervision of a doctor

When using this product

- Avoid contact with the eyes
- Do not begin use any other hydrocortisone product unless directed by a doctor

Stop use and ask a doctor if

- Condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years and older

Apply to the affected area not more than 3 to 4 times daily.

Children under 2 years of age

Do not use. Consult a doctor.

Other Information

Store between 20°-25°C (68°-77°F)

Inactive Ingredients

caprylic/capric triglyceride, caprytyl glycol, cetareth-20, chamomillia recutitia flower extract, citric acid, glycerin, glyceryl, stearate, palmitic acid. petrolatum phenoxyethanol, stearic acid, purified water

Questions or comments?

Call 908 630 9445 weekdays 9:00am to 4:30pm EST or visit us online at www.exederm.com

Principal Display Panel - 2 oz Carton Label

NDC 47832-205-34

exederm[®]

**flare control cream
for eczema & dermatitis**

NET WT 2 OZ (56g)

1% Hydrocortisone Anti-Itch Cream

NDC 47832-205-34

exederm[®]

flare control cream
for eczema & dermatitis



Awarded the
NEA Seal of Acceptance
September 2008

- Helps heal irritated skin
- Fast soothing relief from:
 - ✓ itching
 - ✓ redness
 - ✓ inflammation
 - ✓ rash

ultra sensitive formula for really sensitive skin

Our Philosophy is simple ... Avoid irritants
...always use the mildest ingredients

- No Fragrance
- No Colors or Dyes
- No Propylparaben
- No Methylparaben
- No Propylene Glycol
- No SLS (sodium lauryl sulfate)

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NET WT 2 OZ (56g) 1% Hydrocortisone Anti-Itch Cream

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flare control cream
for eczema & dermatitis

Distributed by:
Bentlin Products LLC,
Basking Ridge,
NJ 07920



1% Hydrocortisone Acetate
Anti-Itch Cream

Made in the USA

Exederm[®] is a registered trademark
©2009

NET WT 2 OZ (56g)

For information on other Exederm products visit: www.exederm.com

Drug Facts (continued)

Stop use and ask a doctor if

- Symptoms persist for more than 7 days or clear up and occur again within a few days
- Condition worsens

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

Apply to the affected area not more than 3 to 4 times daily. Adults and children 2 years and older

Do not use. Consult a doctor. Children under 2 years of age

Other Information

Store between 20°-25°C (68°-77°F).

Inactive ingredients

copolyol, caprylic glycol, cetareth-20, cholethol sulfate, glycerin, hydroxyethyl stearate, palmic acid, petrolatum, phenoxyethanol, stearic acid, purified water

Questions or comments?

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Drug Facts

Active ingredient

Hydrocortisone acetate USP 1.0% w/w

Purpose

Anti-itch

Uses: For temporary relief of itching associated with minor skin irritation. Irritation and rashes due to:

- Atopic eczema
- Contact dermatitis from soaps, detergents or cosmetics
- Diaper dermatitis
- Fleas

Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

For external use only

Do not use

- On children under the age of 2 except under the supervision of a doctor
- On the treatment of diaper rash

When using this product

- Do not begin use of any other hydrocortisone product unless directed by a doctor
- Avoid contact with the eyes

Exederm[®] flare control cream for eczema & dermatitis

Exederm[®] flare control cream for eczema & dermatitis is specially formulated for very sensitive skin and is free from potential irritants such as colors, fragrance and harsh paraben preservatives – why take risks?

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for eczema & dermatitis



NDC 47832-205-34

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<p>Questions or comments? Call 908 630 9445 weekdays 9:00am to 4:30pm EST or visit us online at www.exederm.com</p> <p>Inactive ingredients cetylalcohol, glycerin, polyethylene glycol, cetostearyl alcohol, stearyl alcohol, purified water, glyceryl stearate, palmitic acid, petrolatum, phenoxyethanol.</p> <p>Other information Store between 20°-25°C (68°-77°F).</p> <p>Directions Apply to the affected area not more than 3 to 4 times daily. Adults and children 2 years and older. Children under 2 years of age. Do not use. Consult a doctor.</p> <p>Stop use and ask a doctor if ■ Symptoms persist for more than 7 days or clear up and occur again within a few days. ■ Condition worsens.</p>	<p>Drug Facts</p> <p>Active ingredient Hydrocortisone acetate USP 1.0% w/w.</p> <p>Purpose Anti-itch.</p> <p>Uses: For temporary relief of itching associated with minor skin irritation, inflammation and rashes due to: ■ Contact dermatitis from soaps, detergents or cosmetics ■ Diaper dermatitis ■ Psoriasis</p> <p>Warnings Other uses of this product should be only under the advice and supervision of a doctor. Do not use: ■ For the treatment of diaper rash ■ On children under the age of 2 except under the supervision of a doctor.</p> <p>When using this product ■ Avoid contact with the eyes. ■ Do not begin use of any other hydrocortisone product unless directed by a doctor.</p>
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Exederm® flare control cream is specially formulated for very sensitive skin and is free from potential irritants such as colors, fragrance and harsh paraben preservatives – why take risks?

HYDROCORTISONE ACETATE

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47832-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PALMITIC ACID (UNII: 2V16EO95H1)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CHAMOMILE (UNII: FGL3685T2X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47832-205-34	1 in 1 CARTON	01/24/2007	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:47832-205-15	1 in 1 CARTON	02/07/2018	
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:47832-205-05	576 in 1 CASE	12/08/2014	
3		5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/24/2007	

Labeler - Bentlin Products LLC (832615426)**Registrant** - Sheffield Pharmaceuticals LLC (151177797)**Establishment**

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	MANUFACTURE(47832-205)

Revised: 10/2023

Bentlin Products LLC