

BIOCORNEUM HC ADVANCED SCAR SUPERVISION ANTI-ITCH - hydrocortisone acetate gel
Enaltus Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

bioCorneum HC Advanced Scar Supervision Anti-Itch Gel

Active ingredient

Hydrocortisone acetate 1%

Purpose

Anti-itch

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, soaps, detergents and cosmetics.

Warnings

For external use only

Do not use

- in or near the eyes
- for the treatment of diaper rash: ask a doctor

Stop use and ask a doctor if

- condition worsens, or if 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 immediately.

Directions

- ensure that affected area is clean and dry
- apply evenly in a very thin layer to affected area not more than 3 to 4 times daily
- children under 2 years of age : consult a doctor

Other information

- store below 25 degree (77 degree F)

Inactive ingredients

Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethyl Isosorbide, Pentylene Glycol, Propylene Glycol, Silicon Dioxide

Manufactured in the USA for: enaltus Suwanee, GA 30024 USA 2012 enaltus

bioCorneum HC Advanced Scar Supervision Anti-Itch Gel 5g (43474-000-05)

bioCorneum® HC may reduce redness, soften and flatten scars, and is ideal for new and old scars that itch.

bioCorneum[®] HC
with 1% Hydrocortisone Acetate

advanced
SCAR SUPERVISION
Anti-Itch Gel
NET WT 5g

Manufactured in the USA for:
enaltus™
Suwanee, GA 30024 USA
© 2012 enaltus™

Drug Facts	
Active ingredient	Purpose
Hydrocortisone acetate 1%.....	Anti-itch
Uses	
For the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, soaps, detergents and cosmetics.	
Warnings	
For external use only	
Do not use ● in or near the eyes	
● for the treatment of diaper rash: ask a doctor	
Stop use and ask a doctor if ● condition worsens, or if 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 immediately.	
Directions	
● ensure that affected area is clean and dry	
● apply evenly in a very thin layer to affected area not more than 3 to 4 times daily	
● children under 2 years of age: consult a doctor	
Other information ● store below 25° (77°F)	
Inactive ingredients	
Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethyl Isosorbide, Pentylene Glycol, Propylene Glycol, Silicon Dioxide	



Directions for use: Ensure affected area is clean and dry. Apply evenly in a very thin layer, not more than 3 to 4 times daily.

Warnings: For external use only. Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur within a few days, discontinue use and consult your physician. Keep out of reach of children. Do not use on children under 2 years of age, unless under supervision of a doctor.

Active Ingredient: 1% Hydrocortisone Acetate.

Inactive Ingredients: Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethyl Isosorbide, Pentylene Glycol, Propylene Glycol, Silicon Dioxide.

Manufactured in the USA for:

enaltus™ Suwanee, GA 30024 USA

© 2012 enaltus™

BCPH5USLB-2



What is bioCorneum® HC gel?

bioCorneum® HC is an advanced silicone treatment that was specifically developed with 1% hydrocortisone acetate to provide relief from itch caused by skin irritation and inflammation while treating your scar.

Why has my physician recommended I use bioCorneum® HC gel?

In a recent survey, 42 % of patients experienced itch associated with their scar.¹ In fact, itch is the most common symptom of keloid scars.²

bioCorneum® HC is used for the management of hypertrophic (raised, red) scars and keloids. It can be used on scars resulting from surgical and cosmetic procedures, trauma, wounds, and burns and is effective on old and new scars that itch.

How does bioCorneum® HC work?

bioCorneum® HC gel dries rapidly to form an invisible protective silicone sheet over the affected area. This protective barrier is flexible, waterproof, and breathable. bioCorneum® HC forms a bond with the stratum corneum (the outer layer of dead skin cells) to protect the underlying tissue against chemical, physical and microbial invasion of the scar, while 1% hydrocortisone acetate helps provide temporary relief from itch associated with abnormal scar formation.

The patented silicone formulation in bioCorneum® HC has been shown to flatten, soften, and smooth scars, relieve the itching and discomfort of scars, as well as reduce the discoloration associated with scars.

How is bioCorneum® HC different from other scar products?

In 2002 the International Clinical Recommendations³ were published, and in this publication the physician experts in scar treatment gave only one recommendation for topical (non-invasive) treatment for scars: 100% silicone. It has been proven effective in many clinical studies to reduce scars. There was not enough evidence that any other product worked well enough to earn a recommendation.

Plastic Surgeon Massimo Signorini states that in patients studied, the patented silicone formula "is effective in speeding up maturation and reducing the hypertrophy rate of fresh surgical scars" and that it "could currently be the most recommendable agent for scar treatment, especially in visible areas."⁴

Trust your physician. It is your physician's desire that you have the best aesthetic outcome for your scar. Your doctor has recommended bioComeum[®] HC because he/she is confident that it is an effective product to manage your itch related scar symptoms.

How should bioComeum[®] HC be used?

See **Drug Facts** box for information.

If the gel has not dried within 5 minutes, you have probably used too much. Gently remove the excess and allow the drying process to continue.

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Hydrocortisone acetate 1%.....	Anti-itch

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, soaps, detergents and cosmetics.

Warnings

For external use only

Do not use ● in or near the eyes ● for the treatment of diaper rash: ask a doctor

Stop use and ask a doctor if ● condition worsens, or if 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 immediately.

Directions


- ensure that affected area is clean and dry
- apply evenly in a very thin layer to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information ● store below 25° (77°F)

Inactive ingredients

Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethyl Isosorbide, Pentylene Glycol, Propylene Glycol, Silicon Dioxide

Manufactured in the USA for:

 enaltus[™]
Suwanee, GA 30024 USA

US Patent No. 5,741,509

International Patents

May 2012 • BCPHUSPI-2

¹Data on File ²Shaffer JJ et al. J Am Acad Dermatol. 2002 Feb;46(2 Suppl Understanding):S63-97 ³Mustoe TA et al. Plast Reconstructive Surg 2002; 110:560-71 ⁴Signorini M et al. Aesth Plast Surg 2007; 31:183-187

©2012 enaltus[™]. All rights reserved.

BIOCORNEUM HC ADVANCED SCAR SUPERVISION ANTI-ITCH

hydrocortisone acetate gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43474-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43474-000-05	1 in 1 CARTON		
1		5 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part348	05/10/2012	

Labeler - Enaltus Inc (038868036)

Registrant - Enaltus Inc (038868036)

Establishment

Name	Address	ID/FEI	Business Operations
Formulated Solutions, LLC		143266687	manufacture