Hydrocortisone Butyrate Cream, 0.1% (Lipophilic)
For dermatological use only. Rx only

Each gram contains 1 mg of hydrocortisone butyrate USP in a hydrophilic base consisting of octylene glycol, propylene glycol, butyl alcohol, white petrolatum, sorbitan monostearate, stearol 2-ethylhexanoate, hydroxypropylcellulose, and color. DIRECTIONS: Apply a thin layer to the affected area 2 to 3 times daily, for no longer than 2 weeks, or as directed by your physician. See package insert for complete prescribing information. WARNINGS: Use external use only. Avoid contact with eyes. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Minimum Font Size: 5.5pt.
Hydrocortisone Butyrate Cream, 0.1% (Lipophilic)
For dermatological use only.
Rx only
45 g

Each gram contains: 1 mg of hydrocortisone butyrate USP in a hydrophilic base consisting of cetearyl alcohol, lanolin alcohol, isopropyl palmitate, ceteareth-20, propylene glycol, and purified water.

DIRECTIONS: Apply this ointment to the affected areas 2 to 3 times daily, for no longer than 7 weeks, or as directed by your physician. See package insert for complete prescribing information.

WARNING: For external use only. Avoid contact with eyes. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

Store at 25°C (77°F) excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use hidrocoridine buxyrate cream, 0.1% (Iopiphil) safely and effectively. See full prescribing information for hidrocoridine buxyrate cream, 0.1% (Iopiphil).

HYDROCORIDINE BUTYRATE Cream, 0.1% (Iopiphil)

For topical use only
Initial U.S. Approval: 1992

INDICATIONS AND USAGE

• Hidrocoridine butyrate cream, 0.1% (Iopiphil) is not for oral, ophthalmic, or intranasal use. (2)
• Apply a thin film to the affected skin areas two or three times daily for corticosteroid-receptive dermatoses in adults. (2)
• Apply a thin film to the affected skin areas two times daily for atopic dermatitis in patients 3 months of age and older. (2)
• Rub in gently. (2)
• Discontinue hidrocoridine butyrate cream, 0.1% (Iopiphil) when control is achieved. (2)
• Reasses diagnosis if no improvement is seen within 2 weeks. Before prescription, for more than 2 weeks, any additional benefits of extended treatment to 4 weeks should be weighed against the risk of HPA axis suppression and local adverse events. Safety and efficacy of hidrocoridine butyrate cream, 0.1% (Iopiphil) has not been established beyond 4 weeks of use. (2)

DOSEAGE AND ADMINISTRATION

1. Relief of the inflammatory and pruritic manifestations of corticosteroid-receptive dermatoses in adults.
2. Treatment of mild to moderate atopic dermatitis in patients 3 months to 18 years of age. (1)

DOSE FORMS AND STRENGTHS

2.1 Concomitant use of topical corticosteroids with other topical medications including those containing coal tar, selenium, tar, vitamin A acid, and salicylic acid should be avoided. (2)

CONTRAINDICATIONS

2.2 Intramuscular or intranasal use of corticosteroids increases systemic effects of the corticosteroids and may cause significant adrenal suppression. (2)

ADVERSE REACTIONS

6.1 Clinical Trials Experience: Adults
6.2 Clinical Trials Experience: Pediatrics
6.3 Postmarketing Experience

DRUG INTERACTIONS

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Concomitant Use of Topical Corticosteroids in Adults
2.2 Atopic Dermatitis in Patients From 3 Month to 18 Years

2.3 DOSAGE AND ADMINISTRATION

2.3.1 Hydrocoridine Butyrate Cream, 0.1% (Iopiphil) is not for oral, ophthalmic, or intranasal use. Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Before prescribing for more than 2 weeks, any additional benefits of extended treatment to 4 weeks should be weighed against the risk of HPA axis suppression and local adverse events. Safety and efficacy of hidrocoridine butyrate cream, 0.1% (Iopiphil) has not been established beyond 4 weeks of use. (2)

2.3.2 Hydrocoridine Butyrate Ointment 0.1% (Iopiphil) is not for oral, ophthalmic, or intranasal use. Therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary. Before prescribing for more than 2 weeks, any additional benefits of extended treatment to 4 weeks should be weighed against the risk of HPA axis suppression and local adverse events. Safety and efficacy of hidrocoridine butyrate ointment, 0.1% (Iopiphil) has not been established beyond 4 weeks of use. (2)

3 WARNING AND PRECAUTIONS

5.1 Hypersensitivity-Phototoxic-Adrenal (HPA) Axis Suppression
5.2 Concomitant Skin Infections
5.3 Skin Irritation

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
8.2 Nursing Mothers
8.3 Pediatric Use
8.4 Geriatric Use

11 DESCRIPTION

11.1 Mechanism of Action
11.2 Pharmacokinetics

13 CLINICAL STUDIES

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

14 CLINICAL STUDIES

14.2 Pediatric Atopic Dermatitis

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

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*Sections or subsections omitted from the full prescribing information are not listed.
Hydrocortisone Butyrate Cream, 0.1% (Lipophilic)

For dermatological use only.

Rx only 60 g

Each gram contains: 1 mg of hydrocortisone butyrate in a lipophilic base consisting of cetostearyl alcohol, arachis 165 (glyceryl stearate and PEG 100 stearate), mineral oil, white petrolatum, sorbitan monostearate, anhydrous citric acid, sodium citrate anhydrous, propylparaben, butylparaben and purified water.

DIRECTIONS: Apply a thin layer to the affected areas 2 to 3 times daily, for no longer than 2 weeks, or as directed by your physician. See package insert for complete prescribing information.

WARNING: For external use only. Avoid contact with eyes. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

LOT & EXP. See Crimp.

Manufactured by: Glenmark Generics Inc., USA
Manufactured for: Glenmark Generics Ltd.
Address: Village Kistarpara, Baddi Nalagarh Road
District: Solan, Himachal Pradesh 174101, India
Mfg. Lic. No.: L6959/AM/N6

Questions? 1 (866) 721 7115
www.glenmarkgenerics.com

Minimum Font Size: 6.5pt.

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GLENMARK GENERICS LTD.

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DATE: | |
RA: | Regulatory Text |
QA: | Entire Text |
REMARKS: | |

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Reference ID: 3350650