

## **LOESCH ANTI-ITCH THERAPY- hydrocortisone liquid**

**Loesch Laboratory Consultants, 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.*

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### **Loesch Anti-Itch Therapy**

#### **Active Ingredient**

Hydrocortisone, USP (0.5%)

#### **Purpose**

Anti-Itch

#### **Use**

- Specially formulated to rapidly and completely penetrate the scalp (or skin) delivering itch relief anywhere it's needed.
- This liquid preparation can be applied to the skin or scalp to temporarily relieve minor itching and skin irritations commonly associated with insect bites, poison oak, poison sumac, and skin blemishes.

#### **Warnings**

- Not for use on children under 2 years old except as directed by a pediatrician.
- Avoid contact with eyes and mucous membranes.
- Do not apply to large areas of the body and **do not use** for extended periods of time.
- **For external use only.**
- If irritation develops and persists, discontinue use and **ask a doctor.**
- **When using this product**, if condition worsens or if symptoms persists for more than 7 days or clear up and occur again within a few days, **stop use and ask a doctor.**

**Keep out of reach of children.**

#### **Directions**

- Apply this product topically to affected areas and allow to dry without rubbing.
- Use up to 3 times daily.
- Use only as directed.

#### **Other Information**

- External antipruritic

#### **Inactive Ingredients:**

Ethanol, Purified Water, Isopropyl Alcohol, Glycerin, Laureth 4, t-Butyl Alcohol, Brucine Sulfate

#### **Questions or Comments?**

Loesch Laboratory Consultants, Inc.

4311 South Dr., Houston, TX 77053-4820

800.231.7157 M-F 8am-5pm

Image of 2.0 Fl. Oz. Label  
NDC:25280-004-02

LoeschAntiItchTherapy2oz.jpg

NDC 25280-004-02

## ANTI-ITCH THERAPY

RELIEVES THE ITCHING OF

SKIN & SCALP BLEMISHES  
POISON OAK  
POISON SUMAC  
INSECT BITES

2.0 Fl. Oz.

DRUG FACTS	
<b>Active Ingredient</b> Hydrocortisone, USP (0.5%).....	<b>Purpose</b> Anti-Itch
<b>Use</b> • Specially formulated to rapidly and completely penetrate the scalp (or skin) delivering itch relief anywhere it's needed. • This liquid preparation can be applied to the skin or scalp to temporarily relieve minor itching and skin irritations commonly associated with insect bites, poison oak, poison sumac, and skin blemishes.	
<b>Warnings</b> • Not for use on children under 2 years old except as directed by a pediatrician. • Avoid contact with eyes and mucous membranes. • Do not apply to large areas of the body and do not use for extended periods of time. • For external use only. • If irritation develops and persists, discontinue use and ask a doctor. • When using this product, if condition worsens or if symptoms persists for more than 7 days or clear up and occur again within a few days, stop use and ask a doctor.	
<b>Keep out of reach of children.</b>	
<b>Directions</b> • Apply this product topically to affected areas and allow to dry without rubbing. • Use up to 3 times daily. • Use only as directed.	
<b>Other Information</b> • External antipruritic	
<b>Inactive Ingredients:</b> Ethanol, Purified Water, Isopropyl Alcohol, Glycerin, Laureth 4, t-Butyl Alcohol, Brucine Sulfate	
<b>Questions or Comments?</b> Loesch Laboratory Consultants, Inc. 4311 South Dr., Houston, TX 77053-4820 800.231.7157 M-F 8am-5pm	

## LOESCH ANTI-ITCH THERAPY

hydrocortisone liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:25280-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	5 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAURETH-4 (UNII: 6HQ855798J)	

TERT-BUTYL ALCOHOL (UNII: MD83SFE959)

BRUCINE SULFATE (UNII: KY7O12XPOQ)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:25280-004-02	59.147 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/26/2014	

**Labeler** - Loesch Laboratory Consultants, Inc. (026619510)

**Registrant** - Bio-Medical & Pharmaceutical Manufacturing Corporation (072186356)

### Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(25280-004)

Revised: 6/2014

Loesch Laboratory Consultants, Inc.