

# **HYDROCORTISONE- anti-itch cream ointment**

## **Water-Jel Technologies**

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### **1% Hydrocortisone Cream**

#### **Active ingredient**

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

#### **Purpose**

Anti-itch cream

#### **Uses**

- for the temporary relief of itching associated with minor skin irritations and rashes
- 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. Consult a doctor

##### **When using this product**

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you've consulted a doctor

##### **Stop use and ask a doctor if**

- condition worsens
- symptoms persist more than 7 days
- condition clears up and occurs again within a few days

##### **Keep out of the reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years; do not use, consult a doctor

**Other information**

- clean the affected area
- store at room temperature
- do not use any opened or torn packets
- you may report a serious adverse reaction to this product to 855-428-6074

**Inactive ingredients**

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methylparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, stearic acid, trolamine, water

**Questions ?**

**855-428-6074**

[www.safeguardmedical.com](http://www.safeguardmedical.com)

**Principal Display Panel**

**Drug Facts** (continued)

**Keep out of reach of children.**  
If swallowed contact a Poison Control Center right away.

**Directions** ■ adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily ■ children under 2 years of age: do not use, consult a doctor

**Inactive ingredients**

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate, methyparaben, mineral oil, polyethylene glycol, propylene glycol, propylparaben, stearic acid, trolamine, water

**See box for more information**

Water-Jel Technologies, LLC  
Huntersville, NC 28078 USA 04/24

**WATERJEL®**

**Hydrocortisone Cream 1%**

**Maximum Strength Anti-Itch**

**Drug Facts**

**Active ingredient Purpose**  
Hydrocortisone Anti-itch  
Acetate.....cream

**Uses** ■ for the temporary relief of itching associated with minor irritations and rashes ■ 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. Consult a doctor. Complete Warnings See Card or Box ▶

**NET WT 0.9g (1/32 OZ)**

**HYDROCORTISONE**

anti-itch cream ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59898-800
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HYDROCORTISONE ACETATE</b> (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-800-03	25 in 1 BOX, UNIT-DOSE	04/30/2010	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:59898-800-02	144 in 1 BOX, UNIT-DOSE	04/30/2010	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:59898-800-01	1728 in 1 CARTON	04/30/2010	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:59898-800-36	0.9 g in 1 PACKET; Type 0: Not a Combination Product	04/30/2010	
5	NDC:59898-800-32	28 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2010	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	04/30/2010	

**Labeler** - Water-Jel Technologies (155522589)

## Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 12/2025

Water-Jel Technologies