HYDROCORTISONE - anti-itch cream ointment
Water-Jel Technologies

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.

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
- tamper evident sealed packets
- do not use any opened or torn packets
- you may report a serious adverse reaction to this product to 800-275-3433

Inactive ingredients

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

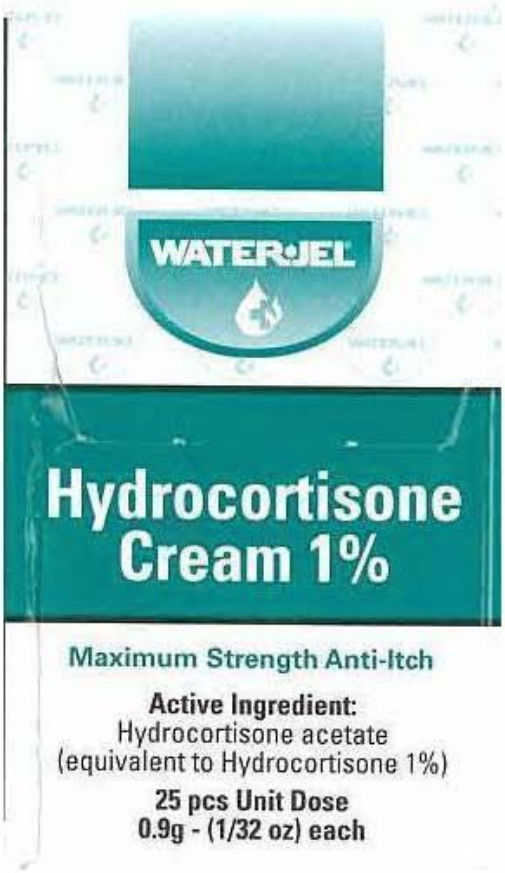
Questions ?

800-275-3433

info@waterjel.com

www.waterjel.com

Principal Display Panel



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HYDROCORTISONE

anti-itch cream ointment

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59898-800
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
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-800-03	25 in 1 BOX, UNIT-DOSE		
1		0.9 g in 1 PACKET		
2	NDC:59898-800-02	144 in 1 BOX, UNIT-DOSE		
2		0.9 g in 1 PACKET		
3	NDC:59898-800-01	1728 in 1 CARTON		
3		0.9 g in 1 PACKET		
4	NDC:59898-800-36	0.9 g in 1 PACKET		
5	NDC:59898-800-32	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/30/2010	

Labeler - Water-Jel Technologies (155522589)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-800)