

PROCURE - hydrocortisone acetate ointment
TWIN MED, LLC

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.

Drug Facts

Active Ingredient (per gram)

Hydrocortisone Acetate, USP (1% w/w)

Purpose

Antipruritic (Anti-Itch)

Uses

For temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, and for external genital, feminine and anal itching. Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

FOR EXTERNAL USE ONLY.

Do not use

- In the eyes
- for diaper rash
- if you have vaginal discharge
- more than recommended dosage.

Ask a doctor before use if

you are pregnant or breast feeding

Stop use and ask a doctor if

- **the condition worsens, or if symptoms persists 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 right away.

Directions

- **Adults and children over 2 years of age**
- Apply evenly to affected area no more than 3 to 4 times daily
- Children under 2 years of age
- Do not use, consult a doctor
- Adults- When practical, cleanse the affected area with mild soap and warm water and rinse

thoroughly

- Gently dry, patting or blotting with bathroom tissue or soft cloth before applying
- apply externally to the area up to 6 times daily or after bowel movement
- After application, discard pad. Do not flush in toilet.

Other Information

- Store at 20°-25°C(68°-77° F)
- Avoid excessive heat and humidity.

Inactive Ingredients

Cetomacrogol 1000, Cetostearyl Alcohol, Chloracresol, Edetate Disodium, Liquid Paraffin, Propylene Glycol, Purified Water, Sodium Metabisulphite, White Soft Paraffin.

Principal Display Panel

NDC # 55681-224-02

ProCure

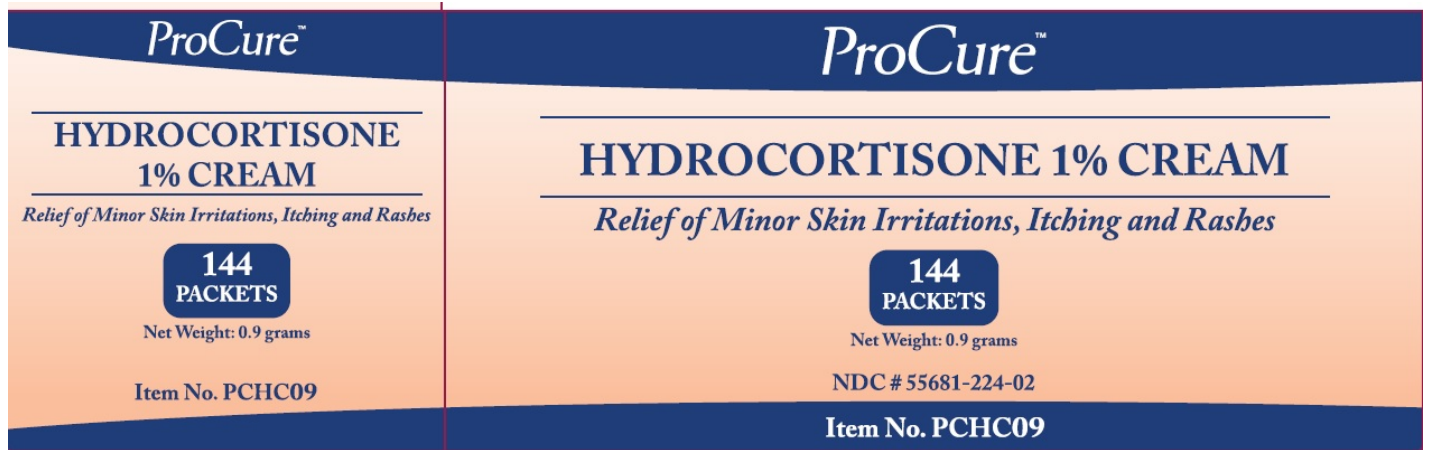
HYDROCORTISONE 1% CREAM

Relief of Minor Skin Irritations, Itching and Rashes

144 PACKETS

Net Weight: 0.9 grams

Item No. PCHC09



PROCURE

hydrocortisone acetate ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5568 1-224
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
CHLOROCRESOL (UNII: 36W53O7109)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55681-224-02	144 in 1 BOX	02/05/2013	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/05/2013	

Labeler - TWIN MED, LLC (009579330)

Registrant - Sion Biotext Medical Ltd (532775194)