

QUADRYDERN- hydrocortisone cream
Productos Zapotol Corp

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.

Quadrydern N.F. Hydrocortisone Cream 2oz (140, ZDP)

Active ingredient Purpose

Hydrocortisone 1%.....Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: eczema, psoriasis, jewelry, insect bites, soaps, cosmetics, detergents, seborrheic dermatitis, poison ivy, oak, sumac
- temporarily relieves external anal and genital 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 genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.
- more than directed unless directed by a doctor.

When using this product

- avoid contact with the eyes
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days and do not begin use of any other hydrocortisone product unless you have consulted a doctor
- rectal bleeding occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- for itching of skin irritation, inflammation, and rashes:
- 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: ask a doctor
- Adults: for external anal itching:

- for external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

- Store at room temperature 20°-25°C (68°-77°F)

Inactive ingredients aloe vera leaf, aluminum sulfate octadecahydrate, calcium acetate monohydrate, cetostearyl alcohol, dextrin, light mineral oil, maltodextrin, methylparaben, petrolatum, propylene glycol, propylparaben, purified water, sodium cetearyl sulfate, sodium lauryl sulfate, white wax

Distributed By:

Productos Zapotol Corp.

Palmdale, CA 93550

Made in China



QUADRYDERN
hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59428-403
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
WHITE WAX (UNII: 7G1J5DA97F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CALCIUM ACETATE MONOHYDRATE (UNII: 7ZA48GIM5H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ALUMINIUM SULFATE OCTADECALHYDRATE (UNII: TCS9L00G8F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59428-403-57	1 in 1 CARTON	03/11/2020	
1		57 g in 1 TUBE; 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	03/11/2020	

Labeler - Productos Zapotol Corp (186063850)