HYDROCORTISONE- hydrocortisone cream
J&A Digital 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.

Hydrocortisone

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

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 superivision of a doctor.

Warnings

For external use only.

Do not use

for the treatment of diaper rash. Consult a doctor.

Stop use and ask a doctor if

- condition worsens of lasts more than 7 days, or clears up and occurs again within a few days.
- you begin use of any other hydrocortisone product
- bleeding occurs

Keep out of reach of children.

If swallowed contact a Poison Control Center right away.

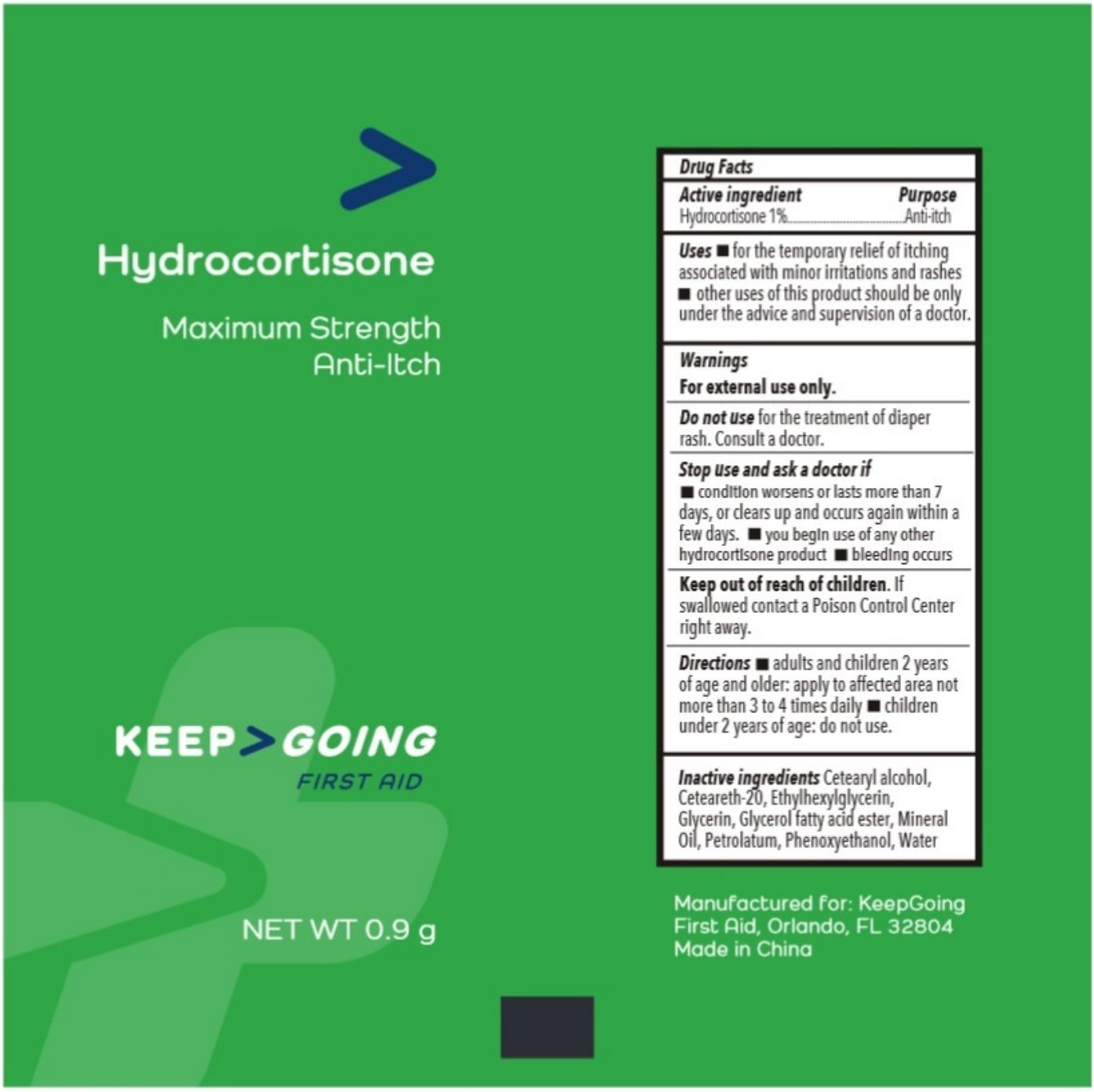
Directions

- 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.

Inactive ingredients

Cetearyl alcohol, Ceteareth-20, Ethylhexylglycerin, Glycerin, Glycerol fatty acid ester, Mineral Oil, Petrolatum, Phenoxyethanol, Water

Package Labeling:



HYDROCORTISONE hydrocortisone cream	
Product Information	

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82942-1003
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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82942-1003-1	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/08/2023	

Labeler - J&A Digital Inc. (040268672)

Revised: 5/2023 J&A Digital Inc.