HYDROCORTISONE- anti-itch cream
Honeywell Safety Products USA, inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

0498-0801: 1% Hydrocortisone Cream

Active ingredient

(In each gram)

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Purpose

Anti-itch cream

Uses

for the temporary relief of itching associated with minor skin irritations and rashes

Warnings

For external use only

Ask a doctor before use if

Ask a doctor before use if you are using any other hydrocortisone product

When using the product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you have consulted a doctor
- do not use for the treatment of diaper rash

Stop use and ask a doctor if

- condition worsens
- condition persists for more than 7 days
- condition clears up and recurs 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 2 years and older:

- clean the affected area
- apply to the area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Other information

- store at room temperature (do not freeze)

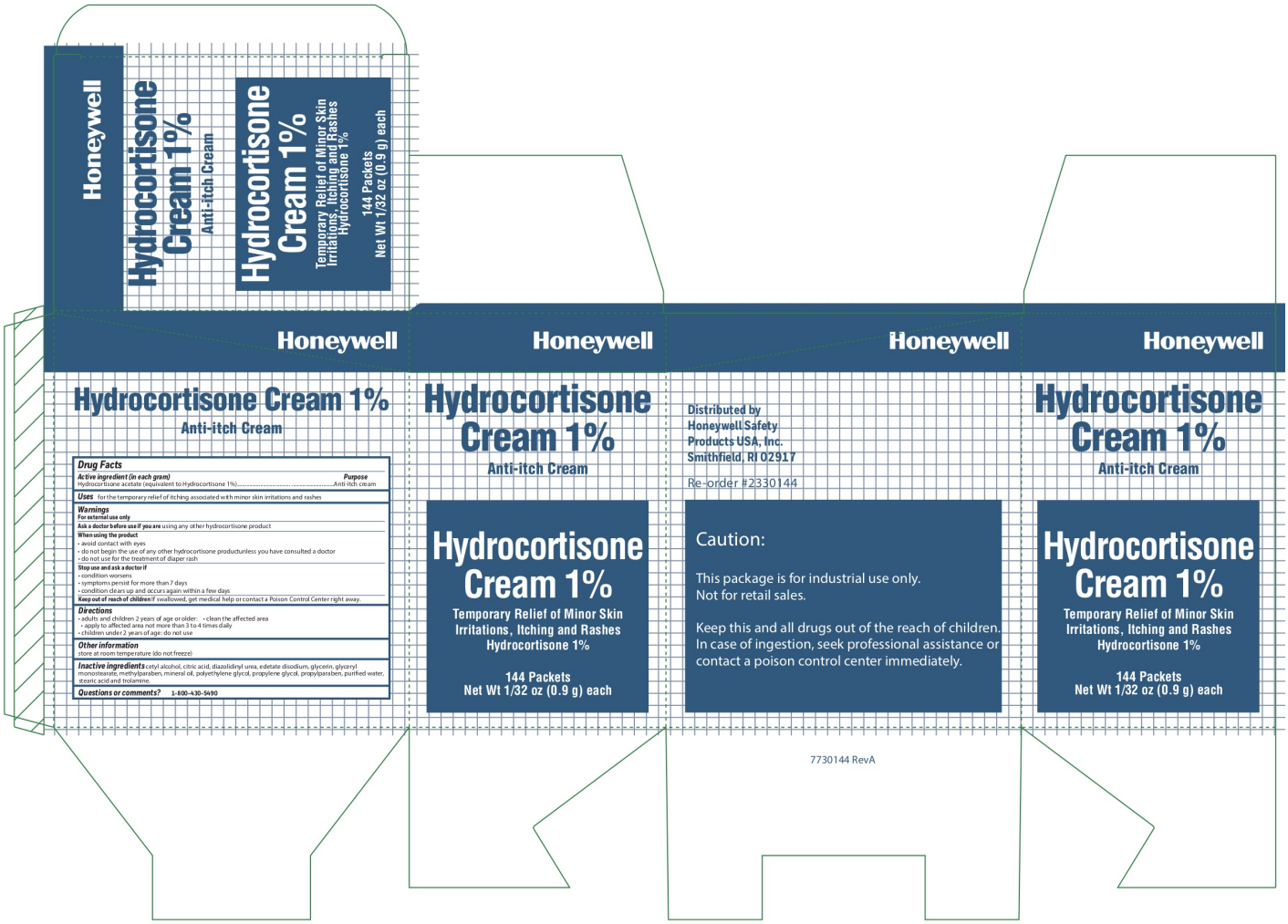
Inactive ingredients

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 or comments?

1-800-430-5490

Principal Display Panel



HYDROCORTISONE

anti-itch cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-0801
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
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0801-03	25 in 1 BOX, UNIT-DOSE	10/15/2019	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0498-0801-02	144 in 1 BOX, UNIT-DOSE	10/15/2019	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0498-0801-01	1728 in 1 CARTON	10/15/2019	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:0498-0801-32	20 in 1 BOX, UNIT-DOSE	10/15/2019	
4		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

5	NDC:0498-0801-33	100 in 1 BOX, UNIT-DOSE	10/15/2019	
5		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:0498-0801-34	10 in 1 BOX, UNIT-DOSE	10/15/2019	
6		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
7	NDC:0498-0801-35	0.9 g in 1 PACKET; Type 0: Not a Combination Product	10/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/15/2019	

Labeler - Honeywell Safety Products USA, inc (118768815)

Registrant - Honeywell Safety Products USA, Inc (118768815)

Revised: 1/2024 Honeywell Safety Products USA, inc