HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone cream
Aru Pharma 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.

QPACK HYDROCORTISONE CREAM 1%

Drug Facts

Active ingredient

Hydrocortisone USP 1%

Purpose

Anti-itch

Uses

• for temporary relief of itching associated with minor skin irritations and rashes due to: • Eczema • Insect bites • Soaps and detergents • Cosmetics • Jewelry • Seborrheic dermatitis • Psoriasis • Poison ivy, oak or sumac • 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 children under 2 years of age • If you have a vaginal discharge • For the treatment of diaper rash

Ask a doctor before use if you have • External genital or feminine itching • External anal itching • Bleeding

When using this product • Avoid contact with eyes • Do not exceed the recommended daily dosage unless directed by a doctor • 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, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use and do not begin use of any other hydrocortisone product, unless you have consulted a doctor.

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

Directions

For minor skin irritations and rashes, adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily. **For external anal itching:**
• **Adults:** when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly • Gently dry by patting or blotting with toilet tissue or soft cloth before application of this product • **Children:** under 12 years of age, consult a doctor.

Inactive ingredients

Cetostearyl Alcohol, Cetomacrogol 1000, Paraffin Wax, Micro Crystalline Wax, Propylene Glycol, Light Liquid Paraffin, Mono basic Sodium Phosphate, Propyl Paraben, Methyl Paraben, Chlorocresol, Purified Water

Other information

• Do not use if seal is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal

• store at room temperature • See crimp of tube or carton for Lot Number and Expiration Date

Questions or comments?

1 844 500-2729 between 9 am and 4 pm EST, Monday to Friday.

MAXIMUM STRENGTH ANTI-ITCH CREAM

Temporary Relief the Discomfort of itching, Rashes and Irritation on Skin Due to Eczema, Psoriasis and Insect bites

Compared to the active ingredient in Cortizone 10

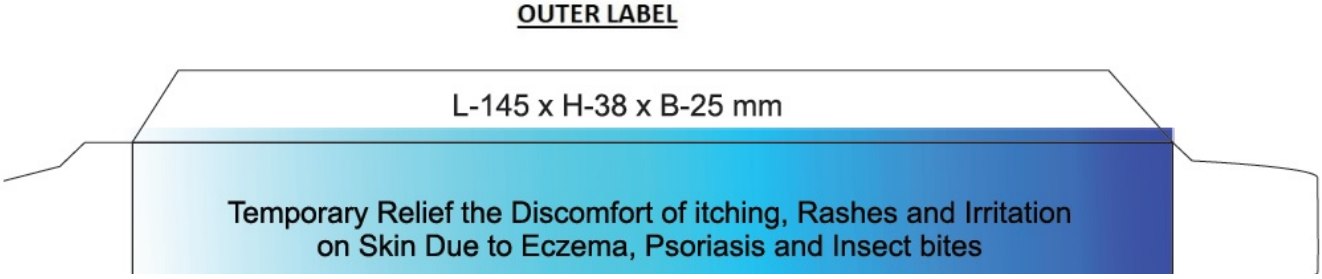
Distributed by.

ARU PHARMA INC.

MOUNT VERNON, NY 10552

www.qpackrx.com

Packaging



QPACK

NDC 70403-923-30
Compared to the active ingredient in Cortizone 10

HYDROCORTISONE
CREAM USP 1%

MAXIMUM STRENGTH ANTI-ITCH CREAM

1 OZ (30g)

NDC 70403-923-30

LOT :

EXP :

Mfg. Lic. No.: TN/DRUGS/28/251
7183600230

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MAXIMUM STRENGTH ANTI-ITCH CREAM
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HYDROCORTISONE
CREAM USP 1%
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QPACK **HYDROCORTISONE**
CREAM USP 1%

ANTI-ITCH CREAM

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NDC 70403-923-30

INNER LABEL

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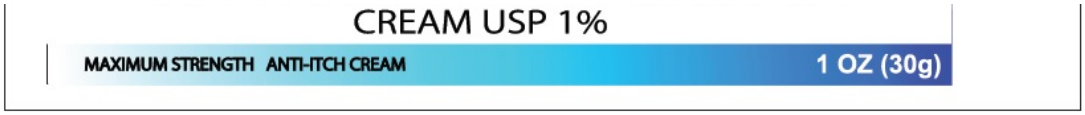
HYDROCORTISONE



HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70403-923
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)	
CETETH-20 (UNII: I835H2IHHX)	
PARAFFIN (UNII: I9O0E3H2ZE)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CHLOROCRESOL (UNII: 36W53O7109)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white (white to off white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70403-923-30	1 in 1 CARTON	01/01/2018	03/31/2025
1		30 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	01/01/2018	03/31/2025

Labeler - Aru Pharma Inc. (079736192)

Revised: 5/2023 Aru Pharma Inc.