

ZCORT ULTRA- hydrocortisone acetate 1% cream
RxDino, 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 Ingredients

Hydrocortisone Acetate 1%

Purpose

Anti-Itch

Uses

Temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:

- Eczema
- psoriasis
- poison ivy, oak, sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

DO NOT USE

- for the treatment of diaper rash
- if pregnant or nursing - consult a doctor
- in the genital area if you have a vaginal discharge - consult a doctor

WHEN USING THIS PRODUCT

- avoid contact with eyes

- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

STOP USE AND ASK A DOCTOR

- if condition worsens or persists for more than 7 days
- if condition clears up and occurs again
- if rectal bleeding occurs
- before using any other hydrocortisone product

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away

Directions

FOR ITCHING OF SKIN IRRITATION, INFLAMMATION, AND RASHES

- adults and children 12 years of age and older apply to affected area not more than 2 to 3 times daily

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 2 to 3 times daily
- Ages 12 to 18 years: ask a doctor

Other Information

Contents filled by weight, not volume

Inactive Ingredients

Aloe Barbadenis Leaf Extract, Cetearyl Alcohol, Cocos Nucifera Oil, Dehydroepiandrosterone (DHEA), Emulsifying Wax, Glycerin, Helianthus Annuus Seed Oil, Phenoxyethanol, Simmondsia Chinensis Seed Oil, Stearic Acid, Tocopherol, Water, Xanthan Gum

Front Display Panel and Back Card

NEW!

FORMULATED TO HEAL ITCH AND PROTECT COLLAGEN

STEROID POWER

FAST ACTING

- Rash

- Poison Ivy
- Eczema
- Insect Bites
- Psoriasis
- Inflammation

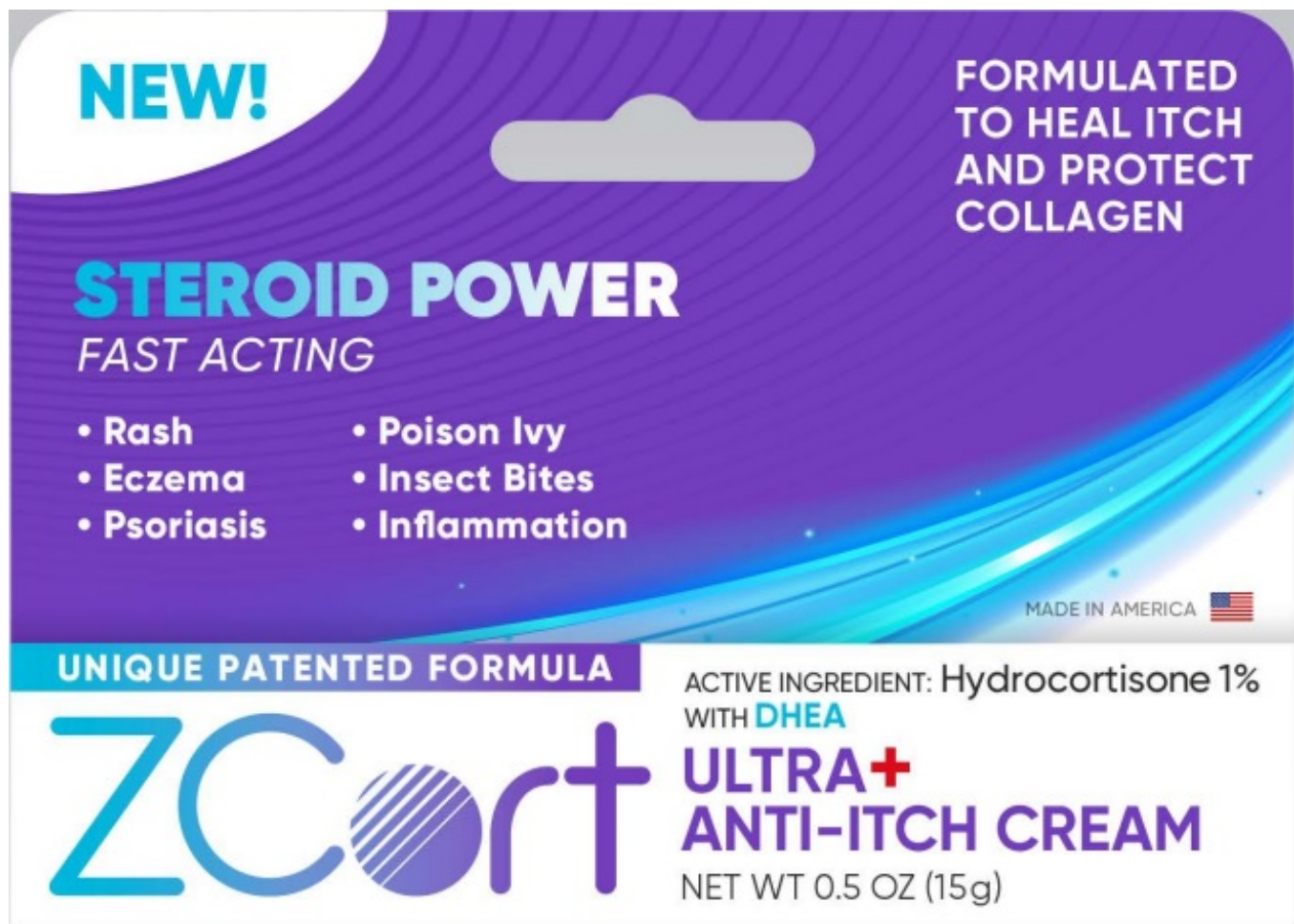
UNIQUE PATENTED FORMULA

ZCort ULTRA+ ANTI-ITCH CREAM

NET WT 0.5 OZ (15g)

ACTIVE INGREDIENT: HYDROCORTIZONE 1% WITH DHEA

see zcortfront.jpg



ZCort Ultra+ ANTI-ITCH CREAM BACK CARD

see zcortbackbox.jpg

ZCort

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ULTRA+ ANTI-ITCH CREAM

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MADE IN AMERICA 

ZCORT ULTRA

hydrocortisone acetate 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81335-532
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: H1E492Z3T)	
PRASTERONE (UNII: 459AG36T1B)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

COCONUT OIL (UNII: Q9L0O73W7L)	
JOJOBA OIL (UNII: 724GKU717M)	
WATER (UNII: 059QF0KO0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81335-532-15	15 g in 1 BOX; Type 0: Not a Combination Product	03/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2021	

Labeler - RxDino, LLC (117804297)

Revised: 1/2023

RxDino, LLC