

PUBLIX HYDRO PLUS- hydrocortisone cream
Publix Super Markets 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.

Publix
hydrocreamplus

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch cream

Uses

- temporary relief of itching associated with minor skin irritations and rashes due to
 - eczema
 - insect bites
 - poison ivy, poison oak, or poison sumac
 - soaps
 - detergents
 - cosmetics
 - jewelry
 - seborrheic dermatitis
 - psoriasis
 - external genital 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 the eyes
- by putting this product into the rectum by using fingers or any mechanical device or applicator

Ask a doctor before use if you have

- a vaginal discharge
- rectal bleeding

- diaper rash

When using this product consult a doctor before exceeding recommended dosage

Stop use and ask a doctor if

- condition gets worse
- condition persists for more than 7 days
- condition clears up and occurs again within a few days. Do not begin to use 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.

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. consult a doctor

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 a soft cloth before application of this product

Children under 12 years of age: consult a doctor

Other information

- To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- store at room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

aloe barbadensis, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, chamomile (anthesis nobilis) oil, citric acid, corn (zea mays) oil, glycerin, glyceryl stearate, isopropyl palmitate, maltodextrin, methylparaben, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Publix

hydrocreamplus

1% HYDROCORTISONE
ANTIPRURITIC (ANTI-ITCH)

12 MOISTURIZERS WITH ALOE FOR ITCH & RASH RELIEF

NET WT 1 OZ (28.4 g)

Publix

hydrocreamplus

1% HYDROCORTISONE
ANTIPRURITIC (ANTI-ITCH)

12 MOISTURIZERS WITH ALOE FOR ITCH & RASH RELIEF

enriched with vitamins A, D & E

Compare to the active ingredient in Cortizone-10® Plus*

LPK-4990-2
0109-2
M185

Publix

hydrocreamplus

1% HYDROCORTISONE
ANTIPRURITIC (ANTI-ITCH)

hydrocreamplus

1% HYDROCORTISONE
ANTIPRURITIC (ANTI-ITCH)

12 MOISTURIZERS WITH ALOE FOR ITCH & RASH RELIEF

NET WT 1 OZ (28.4 g)

T 28

Publix

hydro
cream
plus

1% HYDROCORTISONE

Drug Facts (continued)
Other information
To open unrecapped, pull tab to remove foil seal, and screw cap back onto tube gently by turning or twisting with to let the tube or seal fold before application of this product.
To store at room temperature • see carton or tube for lot number and expiration date
Inactive ingredients also include: sodium lauryl sulfate, sodium lauryl ether sulfate, cetyl alcohol, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate), propylparaben, purified water, polypropylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

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, consult a doctor
For external anal itching:
• take with products to ease the affected area with mild soap and warm water, and rinse thoroughly
• take with products to ease the affected area with mild soap and warm water, and rinse thoroughly
Children under 12 years of age: consult a doctor
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
unless you have consulted a doctor
Do not use:
• in the eyes
• by putting the product into the rectum by using finger or any mechanical device or applicator
Ask a doctor or pharmacist if you have:
• a vaginal discharge • rectal bleeding • diaper rash
When using this product consult a doctor before exceeding recommended dosage
Stop use and ask a doctor if:
• condition gets worse • condition persists for more than 7 days
• condition does not improve within a few days. Do not begin to use any other hydrocortisone product.
Warnings
For external use only
Use:
• temporary relief of itching associated with minor skin irritations and rashes due to:
• eczema • insect bites • poison oak, or poison sumac • soaps • detergents • cosmetics
• jewelry • sebaceous dermatitis • psoriasis • external genital and anal itching
• other uses of this product should be only under the advice and supervision of a doctor.
Drug Facts
Active ingredient
Hydrocortisone 1%
Artichoke cream
Purpose
This product is not manufactured or distributed by Pfizer Consumer Healthcare, Cortizone-10® Plus.

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MADE IN CANADA
publix.com
LAKELAND, FL 33811
SUSSER MARRKETS, INC.
3300 PULASKI CORPORA
PARKWAY
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Publix
1% HYDROCORTISONE
ANTIPRURITIC (ANTI-ITCH)
hydrocreamplus

PUBLIX HYDRO PLUS

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41415-048
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W4X0X7BPJ) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
cetostearyl alcohol (UNII: 2DMT128M1S)	
sodium lauryl sulfate (UNII: 368GB5141J)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
chamomile flower oil (UNII: 60F80Z61A9)	
citric acid monohydrate (UNII: 2968PHW8QP)	
corn oil (UNII: 8470G57WFM)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
maltodextrin (UNII: 7CVR7L4A2D)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
Vitamin A palmitate (UNII: 1D1K0N0VVC)	
cholecalciferol (UNII: 1C6V77QF41)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41415-048-75	1 in 1 CARTON	10/03/1989	
1		28.4 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	10/03/1989	

Labeler - Publix Super Markets Inc (006922009)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41415-048)

Revised: 12/2021

Publix Super Markets Inc