

PEDIADERMICS ECZEMA 2- hydrocortisone spray
RENU LABORATORIES, LLC

PEDIADERMICS ECZEMA 2

pediadermics Eczema 2 flare control spray

Active Ingredients:

Hydrocortisone 1%

Purpose

Anti-itch

Uses:

For the temporary relief of minor skin irritations, inflammation and rashes due to eczema

Warnings For external use only

When using this product

- Avoid direct contact with eyes, mouth, genitals/anus
- Do not use for treatment of diaper rash without consulting a physician first

Stop use and ask a doctor if

- Condition worsens or irritation occurs
- Symptoms last more than 2 weeks

Keep out of reach of children

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

Directions

For best results follow **the rule of "2s" ...**

- Consult a physician before using on children under "2" years of age
- Give the bottle at least "2" good shakes before using
- Hold the bottle about "2" inches from the skin
- Dispense at least "2" full pump sprays onto areas of flaring (red, rough, itchy) skin
- Cover flaring areas of skin completely plus about "2" finger-widths onto normal skin
- Use "2" times a day for no more than "2" weeks straight.
- Go to a physician if rash persists for more than "2" weeks

Inactive Ingredients

1, 2 Hexanediol, Avena Sativa (Oat) Kernel Extract, Carbomer, Ceramide AP, Ceramide EOP, Ceramide NP, Cholesterol, Citric Acid, Deionized Water, Glycerin (Vegetal), Maltodextrin, UMF-20 Manuka Honey (20%), Ophiopogon Japonicus (Dwarf Lilyturf) Root Extract, Phytosphingosine, Sodium Citrate, Sodium Hyaluronate, Sodium Lauroyl Lactylate, Sorbitol, Xanthan Gum

Manufactured for Pediadermics LLC

Bethlehem PA 18018

www.pediadermics.com

BOTTLE ARTWORK

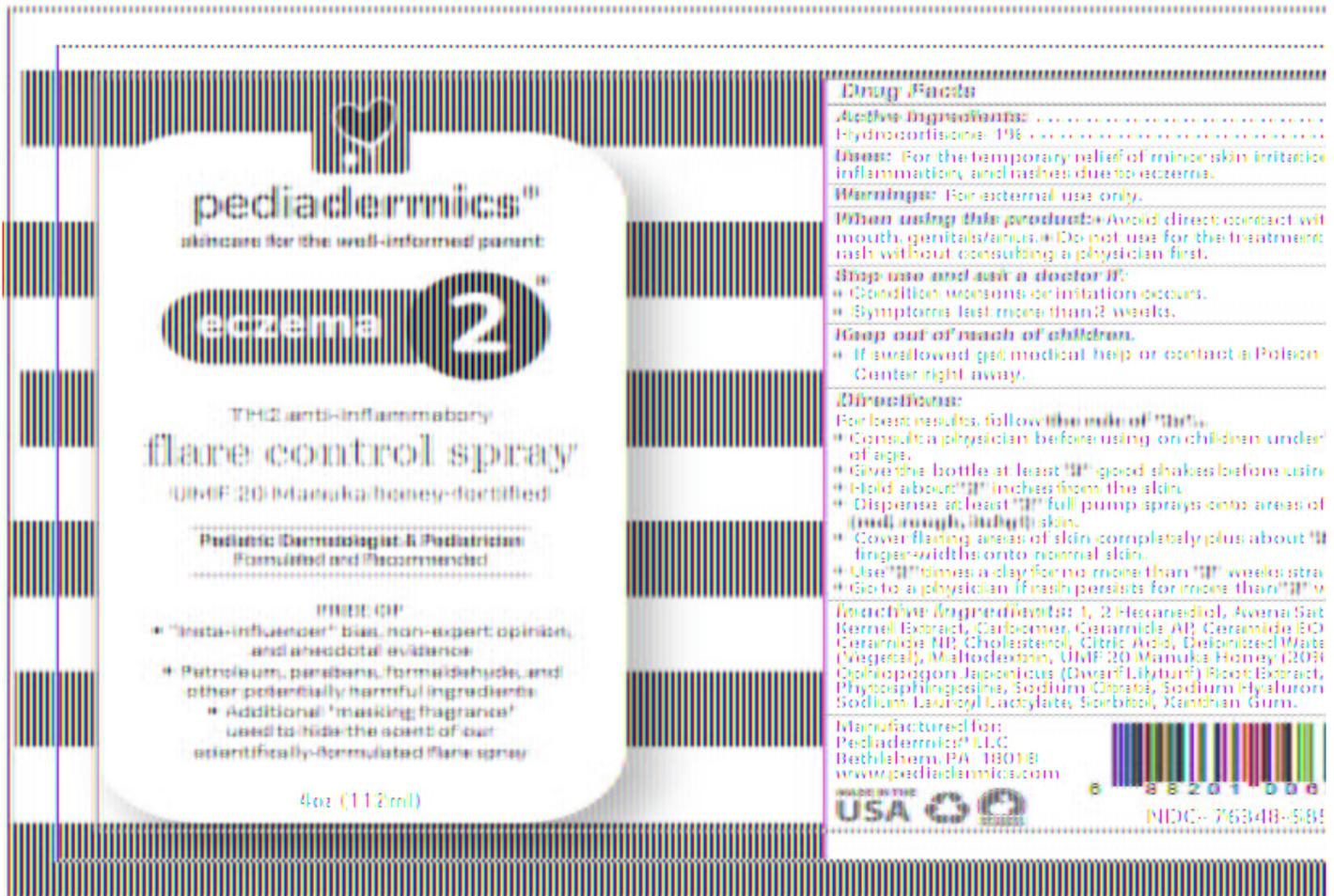
3.375 x 4.5

4oz PET Bottle

Live area

Cut Line

Bleed



PEDIADERMICS ECZEMA 2

hydrocortisone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-585
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1.12 g in 112 g

Inactive Ingredients

Ingredient Name	Strength
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
SORBITOL SOLUTION 70% (UNII: 8KW3E207O2)	
OAT (UNII: Z6J799EAJK)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
HONEY (UNII: Y9H1V576FH)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CERAMIDE NP (UNII: 4370DF050B)	
CERAMIDE AP (UNII: F1X8L2B00J)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-585-04	112 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/18/2022	

Labeler - RENU LABORATORIES, LLC (119451815)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, LLC		119451815	manufacture(76348-585)