PEDIADERMICS ECZEMA 2- hydrocortisone spray
RENU LABORATORIES, 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.

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 botle 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

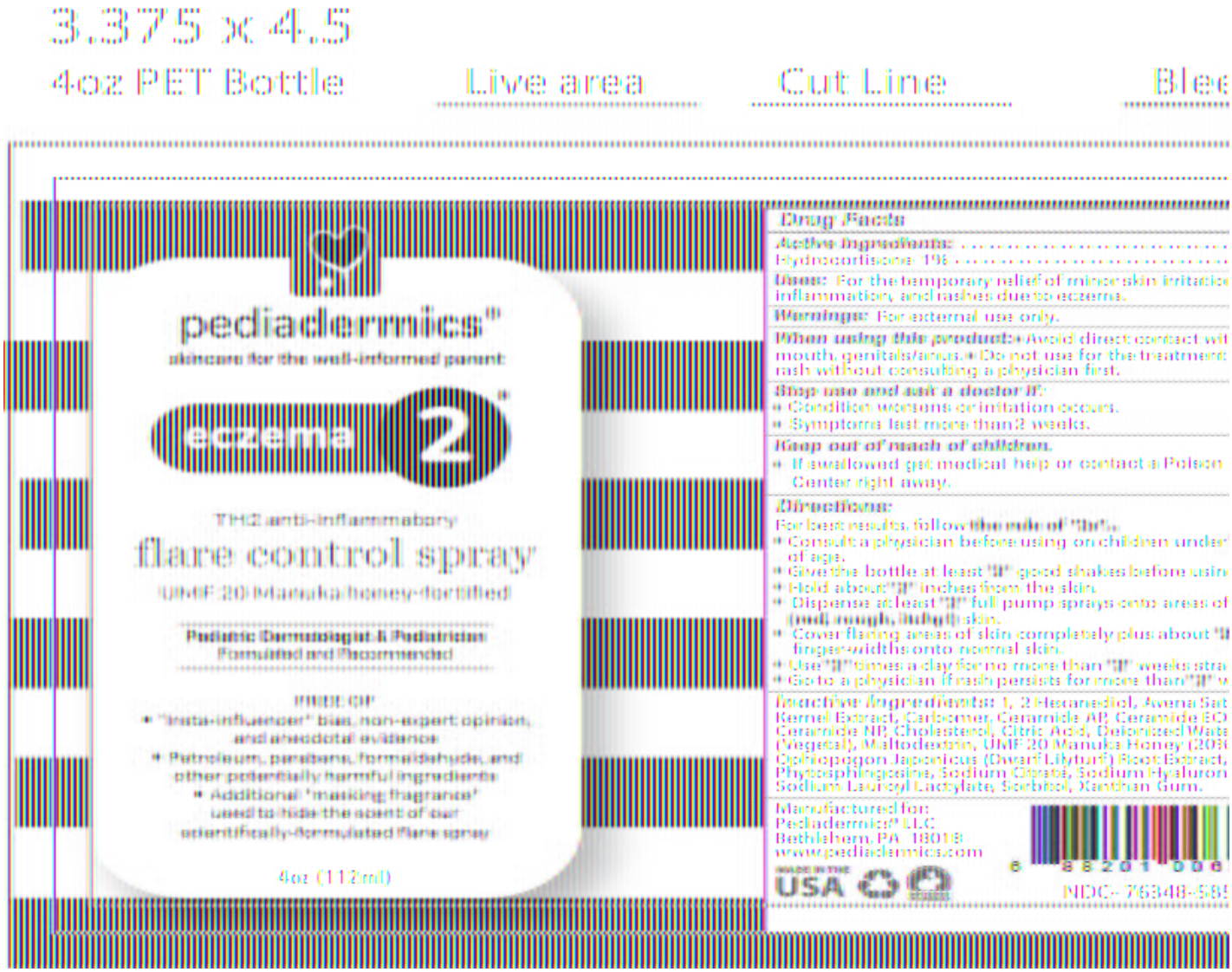
Extract, Phytosphingosine, Sodium Citrate, Sodium Hyaluronate, Sodium Lauroyl Lactylate, Sorbitol, Xanthan Gum

Manufactured for Pediadermics LLC

Bethlehem PA 18018

www.pediadermics.com

BOTTLE ARTWORK



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 not final	part348	03/18/2022	

Labeler - RENU LABORATORIES, INC. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
RENU LABORATORIES, INC.		945739449	manufacture(76348-585)