HYDROCORTISONE- antipruritic (anti-itch) cream
Dynarex Corporation

1137 Hydrocortisone 1% Cream NDC 67777-004-04
1139 Hydrocortisone 1% Cream NDC 67777-004-01
1137UB-6 Hydrocortisone 1% Cream NDC 67777-004-05
1137-25 Hydrocortisone 1% Cream NDC 67777-004-07

Active Ingredients

Hydrocortisone USP 1%

Purpose

Antipruritic (Anti-Itch)

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis, and for external genital, feminine, and anal itching.

Warnings

For External Use Only

If pregnant or breast-feeding,

Ask a health professional before use

Do not use

- In the eyes
- For diaper rash
- For external genital or feminine itching if you have a vaginal discharge
- More than the recommended daily dosage unless directed by a doctor
- In 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 (do not continue to use this or any other hydrocortisone product for longer than 7 days)
- Bleeding occurs due to anal itching

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222)

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:** Consult a doctor.
- When used for anal itching, cleanse the affected area with mild soap and warm water and rinse thoroughly, gently dry by patting or blotting with bathroom tissue or soft cloth before applying.
- **Children under 12:** Consult a doctor before using for anal itching.

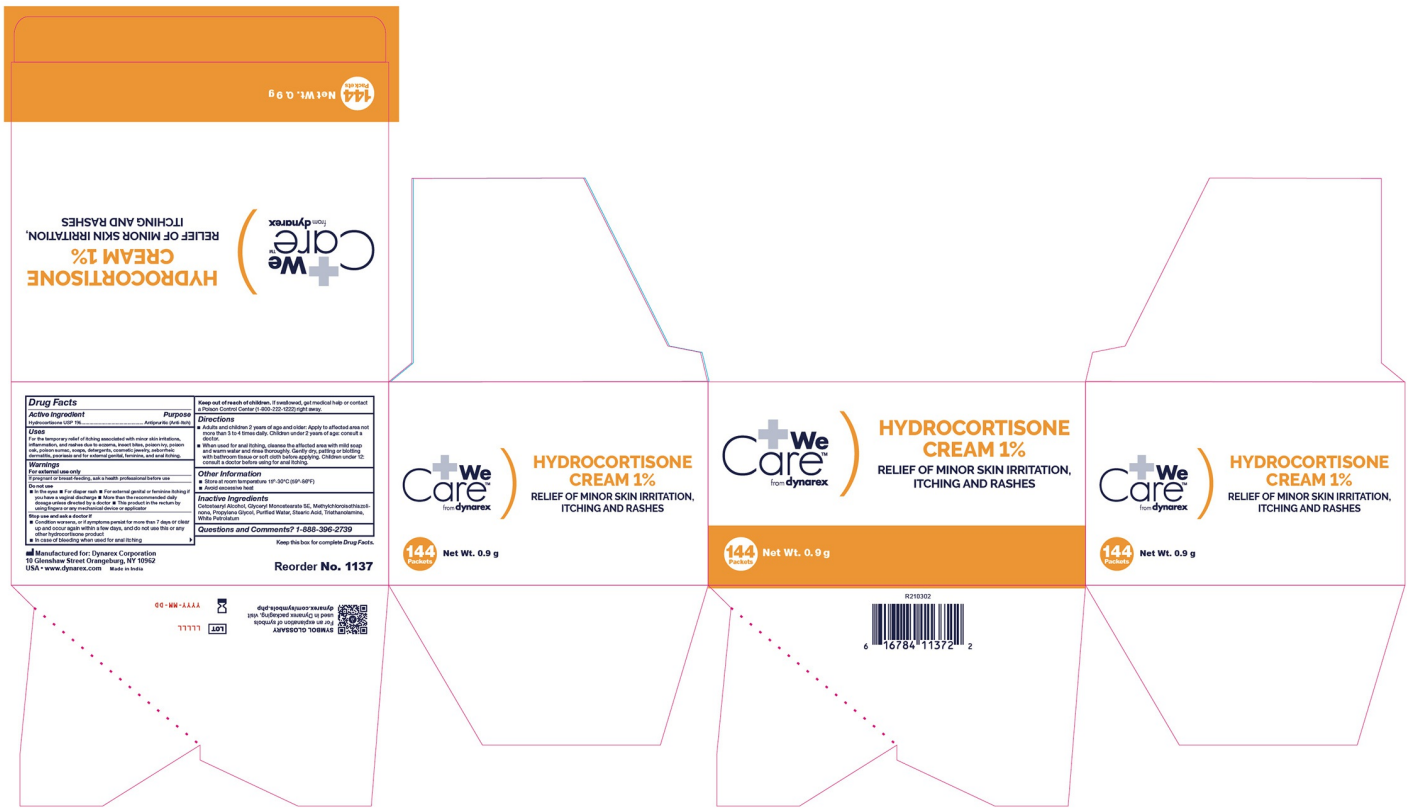
Other Information

- Store at room temperature 15º-30ºC (59º-86ºF)
- Avoid excessive heat
- Tamper Evident. Do not use if seal is damaged.

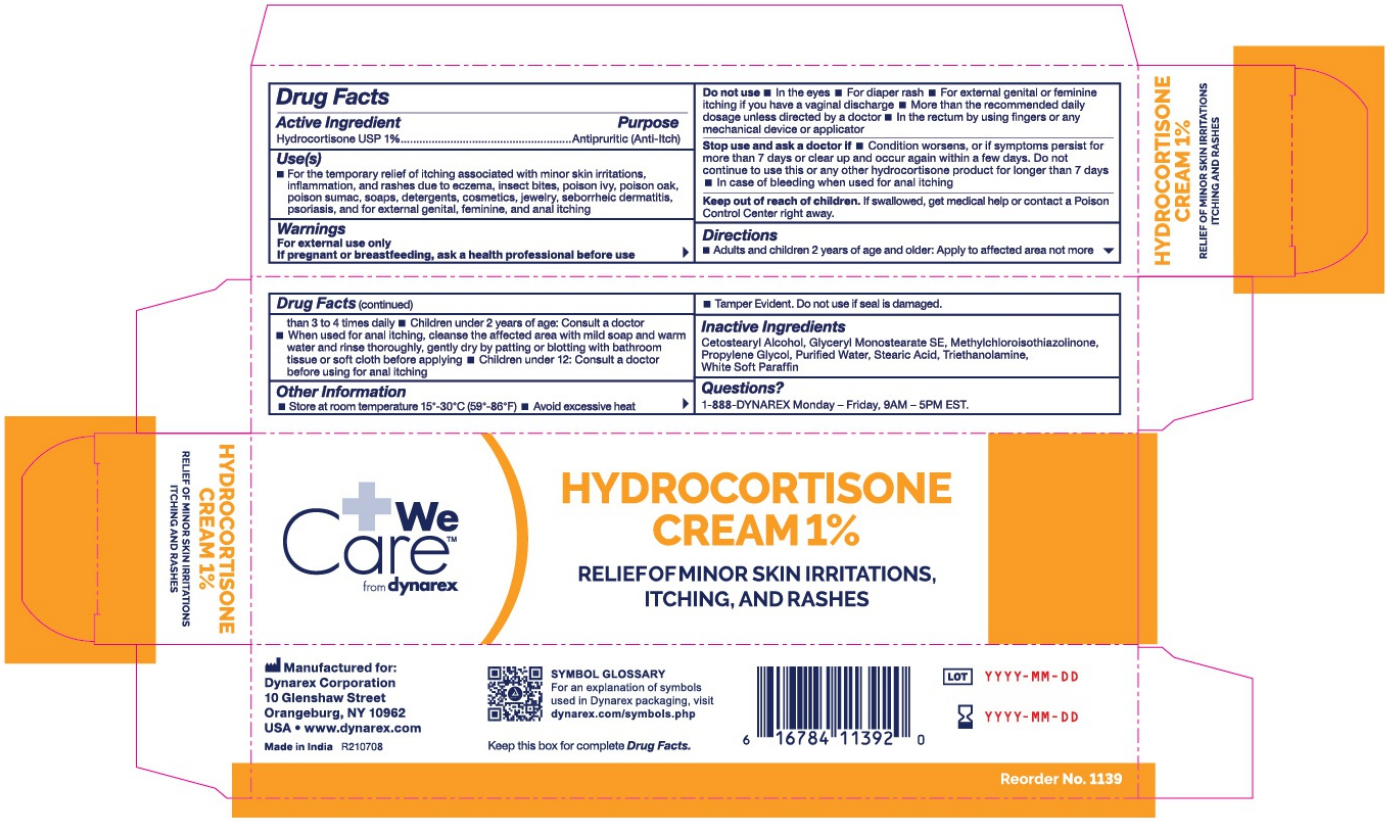
Inactive Ingredients

Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine, White Petrolateum

Label



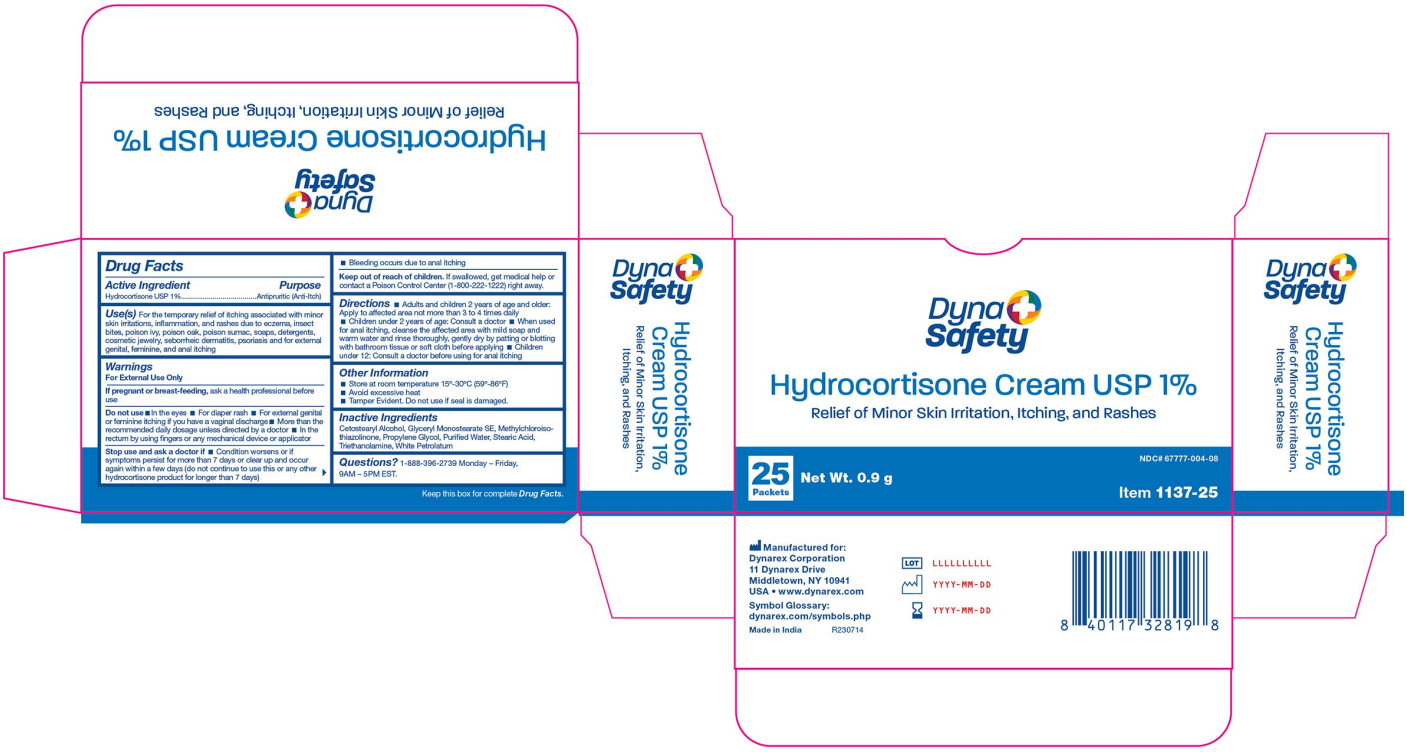
Label



Label 1137UB-6

1137UB-6

Label 1137-25



1137-25

HYDROCORTISONE

antipruritic (anti-itch) cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-004
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**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Product Characteristics

Color		**Score**	
Shape	FREEFORM	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-004-04	12 in 1 CASE	03/25/2021	
1	NDC:67777-004-03	144 in 1 BOX		
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67777-004-01	72 in 1 CASE	03/25/2021	
2	NDC:67777-004-02	1 in 1 BOX		
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:67777-004-05	600 in 1 CASE	03/25/2021	
3	NDC:67777-004-06	6 in 1 BOX		
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:67777-004-07	1800 in 1 CASE	03/25/2021	
4	NDC:67777-004-08	25 in 1 BOX		
4		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	03/25/2021	

Labeler - Dynarex Corporation (008124539)

Revised: 1/2024

Dynarex Corporation