MEDI-FIRST PLUS HYDROCORTISONE- 1 % hydrocortisone cream MEDI-FIRST HYDROCORTISONE- 1 % hydrocortisone cream Unifirst First Aid Corporation

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.

Medi-First 1% Hydrocortisone Cream

Drug Facts

Active ingredient

Hydrocortisone 1.0%

Purpose

Antipruritic (ant-itch)

Uses

- for the temporary relief of itching associated with minor skin irritations, inflammation and rashes
- for external genital, feminine, 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

- for the treatment of diaper rash
- with any other Hydrocortisone product unless you have consulted a doctor
- if you have a vaginal discharge, consult a doctor

When using this product

- avoid contact with eyes
- do not put this product into rectum by using fingers, mechanical device or applicator
- do not exceed recommended daily dosage unless directed by a doctor

Stop use and ask a doctor if

 condition worsens, symptoms persist for more than 7 days or symptoms clear up and reappear again within a few days and do not begin use of any other hydrocortisone product • rectal bleeding occurs

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 and ask a doctor

For external anal and genital itching in adults:

- when practical, clean 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

Children under 12 years of age: ask a doctor

Other information

- store at room temperature 59° to 86° F (15° to 30° C)
- tamper evident, do not use if packet is torn, cut or opened
- avoid excessive heat and humidity

Inactive ingredients

benzoic acid, chlorphenesin, citric acid, glycerin, glyceryl monostearate, methylparaben, mineral oil, petrolatum, phenoxyethanol, polysorbate 80, purified water, titanium dioxide, trisodium citrate

Questions or comments?

1-800-634-7680

Medi-First 1% Hydrocortisone Cream Label

Medi-First®

1% Hydrocortisone Cream

Temporary relief of itching associated with minor skin irritation and rashes

Item # 21173

0.9g (1/32oz) Packets

25 per box



Medi-First Plus 1% Hydrocortisone Cream Label

Medi-First® Plus

Hydrocortisone Cream 1%

Temporary relief of itching associated with minor skin irritation and rashes

25 Units of 0.9g (1/32oz) Packets

Item # 93373



MEDI-FIRST PLUS HYDROCORTISONE

1 % hydrocortisone cream

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:47	NDC:47682-633	
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Ingredient Name Basis of Strer				ength	Strength	
HYDROCORTISONE (UNII: W4X0X	7BPJ) (HYDROCORTISONE -	UNII:W4X0X7BPJ)	HYDROCORTISC	DNE	10 mg in 1 g	
Inactive Ingredients						
Ingredient Name			S	Strength		
METHYLPARABEN (UNII: A218C7HI	9T)					
PHENOXYETHANOL (UNII: HIE4922	ZZ3T)					
POLYSORBATE 80 (UNII: 60ZP392	ZG8H)					
TITANIUM DIOXIDE (UNII: 15FIX9V	(2JP)					

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-633- 73	25 in 1 BOX	01/01/2020	12/01/2024
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
M	larketing	Information		

01/01/2020

12/01/2024

OTC monograph not final

part348

MEDI-FIRST HYDRO	CORTISONE				
1 % hydrocortisone cream					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So	urce)	NDC:47	682-611
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingre	edient Name		Basis of Str	ength	Strength
HYDROCORTISONE (UNII: W4X0X	7BPJ) (HYDROCORTISONE -	UNII:W4X0X7BPJ)	HYDROCORTISC	DNE	10 mg in 1 g
Institute Ingradiante					
Inactive Ingredients					
	Ingredient Name			S	trength
PETROLATUM (UNII: 4T6H12BN9U)				
WATER (UNII: 059QF0K00R)					
MINERAL OIL (UNII: T5L8T28FGP)					
GLYCERYL MONOSTEARATE (UN	II: 2300U9XXE4)				
CHLORPHENESIN (UNII: 1670DAL4	SZ)				
CITRIC ACID MONOHYDRATE (UN	NII: 2968PHW8QP)				

BENZOIC ACID (UNII: 85KN0B0MIM)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Packaging

5 5					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:47682-611- 35	144 in 1 BAG	01/01/2020	12/01/2024	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:47682-611- 73	25 in 1 BOX	01/01/2020	12/01/2024	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product			
3	NDC:47682-611- 12	10 in 1 BOX	01/01/2020	12/01/2024	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product			
4	NDC:47682-611- 99	0.9 g in 1 PACKET; Type 0: Not a Combination Product	01/01/2020	12/01/2024	
Marketing Information					
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OT fin	C monograph not al	part348	01/01/2020	12/01/2024	

Labeler - Unifirst First Aid Corporation (832947092)

Revised: 8/2023

final

Unifirst First Aid Corporation