HYDROCORTISONE- drs. hydrocortisone cream
OL PHARMA TECH,LLC

ACTIVE INGREDIENT

Hydrocortisone, USP 1%

PURPOSE

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 ...

WARNINGS

For external use only

DO NOT USE

for external feminine itching if you have a vaginal discharge. Consult a doctor.
for the treatment of diaper rash. Consult a doctor.

WHEN USING THIS PRODUCT

•avoid contact with the eyes

•do not begin the use of any other hydrocortisone product unless directed by a doctor

•for external anal itching:

do not use more than directed unless directed by a doctor

do not put this product into the rectum by using fingers or any mechanical device or applicator

STOP USE AND ASK YOUR DOCTOR IF

•symptoms last for more than 7 days

•the condition gets worse

•symptoms clear up and occur again in a few days

•rectal bleeding occurs, consult doctor promptly

KEEP OUT OF REACH OF CHILDREN

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, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product

OTHER INFORMATION

- Store at room temperature 59°-86°F (15°-30°C).
- Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

INACTIVE INGREDIENTS

cetostearyl alcohol, sodium cetostearyl sulfate, stearic acid, trolamine, mineral oil , propylene glycol, water, methyl paraben, propyl paraben, EDTA, vitamin E

original strenghth

fast itch relief cream

HYDROCORTISONE

drs. hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80489-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETEARETH-12 (UNII: 7V4MR24V5P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80489-001-01	1 in 1 CARTON	01/01/2021	
1		28.3 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:80489-001-02	1 in 1 CARTON	01/01/2021	
2		49.5 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 Drug	M016	01/01/2021	

Labeler - OL PHARMA TECH,LLC (021170377)

Registrant - OL PHARMA TECH,LLC (021170377)

Establishment

Name	Address	ID/FEI	Business Operations
OL PHARMA TECH,LLC (Drs. pharmacy)		021170377	manufacture(80489-001)