

POLI-A- hydrocortisone acetate ointment
Sato Pharmaceutical Co., Ltd.

Poli-A

Uses

For the temporary relief of itching associated with minor skin irritations and rashes due to

- eczema ■insect bites ■poison ivy ■poison oak ■poison sumac
- soaps ■detergents ■cosmetic ■jewelry
- seborrheic dermatitis ■psoriasis ■external 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. Consult a doctor.

When using this product

- avoid contact with the eyes
- do not exceed the recommended daily dosage unless directed by a doctor (for external anal itching)
- consult a doctor promptly in case of bleeding (for external anal itching)
- do not put this product into the rectum by using fingers or any mechanical device or applicator (for external anal itching)

Stop use of this or any other hydrocortisone product and ask a doctor if

- condition worsens ■symptoms persist for more than 7 days.
- symptoms clear up and occur again within a few days.

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

(When used for external anal itching)

- adults and children 12 years of age and older: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. gently dry by patting or

blotting with toilet tissue or soft cloth before application of this product

■ children under 12 years of age: consult a doctor

Other information keep tube tightly closed

Inactive ingredients fragrance, glyceryl monostearate, light mineral oil, white petrolatum, zinc oxide

Active ingredient

Hydrocortisone acetate 1.0%

Purpose Antipruritic (anti-itch)



POLI-A			
hydrocortisone acetate ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49873-703
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII: W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49873-703-01	1 in 1 CARTON	03/19/1995	
1		20 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	M017	03/19/1995	

Labeler - Sato Pharmaceutical Co., Ltd. (690575642)

Establishment

Name	Address	ID/FEI	Business Operations
Sato Pharmaceutical Co., Ltd.		715699133	manufacture(49873-703) , label(49873-703) , pack(49873-703)

Revised: 11/2023

Sato Pharmaceutical Co., Ltd.