ASTONEA- hydrocortisone cream
ASTONEA LABS PRIVATE LIMITED

ASTONEA Hydrocortisone

Active Ingredient

Hydrocortisone Acetate USP (1% w/w)

Purpose

Anti-itch

Uses

■ for temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, and 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

■ in the eyes ■ for diaper rash ■ if you have vaginal discharge ■ more than the recommended dosage

Ask a doctor before use

■ if you are pregnant or breast feeding

Stop use and ask a doctor if

■ the condition worsens, or if symptoms persist for more than 7 days or clear up and occur again wihin 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 over 2 years of age

■ apply evenly to affected area no more than 3 to 4 times daily

■ children under 2 years of age■ do not use, consult a doctor

■ **Adults**

■ when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly

■ gently dry, patting or blotting with bathroom tissue or soft cloth before applying

■ apply externally to the area up to 6 times a daily or after a bowel movement

■ after application discard pad

■ do not flush in toilet

Other information

■ store at 20-25C (68-77F)

■ avoid excessive heat and humidity

Inactive Ingredients

cetostearyl alcohol, chlorocresol, ceteth-20, edetate disodium, liquid paraffin, propylene glycol, purified water, sodium metabisulphite, white soft paraffin

Package Label

ASTONEA

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77338-305
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
CETETH-20 (UNII: I835H2IHHX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-305-02	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/02/2022	
2	NDC:77338-305-03	28.3 g in 1 TUBE; Type 0: Not a Combination Product	05/02/2022	
3	NDC:77338-305-06	454 g in 1 JAR; Type 0: Not a Combination Product	05/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/02/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Establishment

Name	Address	ID/FEI	Business Operations
ASTONEA LABS PRIVATE LIMITED		878533295	manufacture(77338-305)