REPHRESH COOLING- hydrocortisone spray Church & Dwight Co., Inc.

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.

RepHresh Spray

Hydrocortisone 0.5%

External Analgesic/Anti-Itch

USE

For the temporary relief of external feminine itching

Other uses of this product should be only under the advice and supervision of a doctor

Warning(s) For external vaginal use only

Do not use if you have vaginal discharge

Consult a doctor if you are allergic to any ingredient in this product

When using this product

Avoid contact with eyes

Do not use more than directed unless told to do so by a doctor

Stop use and ask a doctor if condition worsens, symptoms persists for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have consulted a doctor

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Adults and children under 12 years of age and older: Apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: Do not use, consult a doctor

When practical, cleanse and dry the affected area before application of this product

Remove safety seal and cap

Pump 3-5 times before first use for proper dispensing

Shake gently before applying

Holding tube 6 inches away from vaginal are and apply using 1 quick, firm spray.

Note: Tube is designed to spray upside down, if needed

Keep away from hear or direct sunlight, store at room temperature

Do not use if safety seal is broken or missing

Water, Propanediol, Propylene Glycol, Pentylene Glycol, Laureth-9, Polysorbate 20, Chamomilla Recutita (Matricaria) Flower Extract, Menthyl Ethylamido Oxalate, Citronellyl Methylcrotonate, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Lactic Acid

Questions? Call us at $800\ 833\ 9532\ Monday$ through Friday 9 to 5 pm ET or visit our website at www rephresh com

RepHreshTM Vaginal Anti-Itch Spray

Cooling Relief Spray

#1 Trusted Brand

Gynecologist Recommended

Unscented

0.50 FL OZ (15mL)

0.5% Hydrocortisone



hydrocortisone spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10237-774	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	500 g in 1 g		

Inactive Ingredients	
Ingredient Name	Strength
MATRICARIA CHAMO MILLA (UNII: G0 R4UBI2ZZ)	
CITRO NELLYL METHYLCROTO NATE (UNII: K610222P3D)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLIDO CANOL (UNII: 0 AWH8 BFG9 A)	
PROPANEDIOL (UNII: 5965N8W85T)	
MENTHYL ETHYLENE GLYCOL CARBONATE, (-)- (UNII: 4K3514B1GT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MATRICARIA CHAMOMILLA FLO WERING TOP (UNII: 3VNC7T6Z02)	
POLYSORBATE 20 (UNII: 7T1F30 V5YH)	

]	Packaging				
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:10237-774- 15	1 in 1 CARTON	06/01/2018		
1		15 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2018	

Labeler - Church & Dwight Co., Inc. (001211952)

Registrant - Church & Dwight Co., Inc. (001211952)

Establishment

Name	Address	ID/FEI	Business Operations
FLEET LABORATORIES LTD		217269489	manufacture(10237-774)

Revised: 6/2018 Church & Dwight Co., Inc.