

**REPHRESH COOLING- hydrocortisone spray**  
**Fleet Laboratories LTD**

*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.*

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**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

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

Avoid contact with eyes

Do not use if you have vaginal discharge

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.fleetlabs.com](http://www.fleetlabs.com)

rephresh.com

RepHresh™ Vaginal Anti-Itch Spray

Cooling Relief Spray

#1 Trusted Brand

Gynecologist Recommended

Unscented

0.50 FL OZ (15mL)

0.5% Hydrocortisone

SPRAYS UPSIDE DOWN

RepHresh™  
VAGINAL ANTI-ITCH  
SPRAY

COOLING RELIEF  
SPRAY



Unscented  
0.50 FL OZ (15mL)  
0.5% HYDROCORTISONE

Made in UK. Manufactured for Church & Dwight Co., Inc. Ewing, NJ 08628 USA

**Active Ingredient:** Hydrocortisone 0.5% **Purpose:** External Analgesic/Anti-Itch **Use(s)** ■ For the temporary relief of external feminine itching ■ Other uses of this product should be only under the advice and supervision of a doctor. **Warnings!** For external vaginal use only. **Do Not Use** ■ If you have a vaginal discharge. Consult a doctor ■ If you are allergic to any ingredient in this product. **When using this product** ■ Avoid contact with the eyes ■ Do not use more than directed unless told to do so by a doctor. **Stop using and ask a doctor if** ■ condition worsens, symptoms persist 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 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 external vaginal area and apply using 1 quick, firm spray. Note: Tube is designed to spray upside down, if needed. **Other Information** ■ keep away from heat or direct sunlight, store at room temperature ■ Do not use if safety seal is broken or missing. **Inactive Ingredients** Water, Propylparal, Propylene Glycol, Perylene Glycol, Laureth-9, Polysorbate 20, Chamomilla Recutita (Matricaria) Flower Extract, Menthyl Ethylamido Oxalate, Citronellyl Methylcrotonate, Aloe Barbaderensis/Aloe Vera Leaf Juice Powder, Lactic Acid. **Questions?** Call us at 1-800-833-8532 (M-F 9am-5pm ET) or visit our website at [www.rephresh.com](http://www.rephresh.com) 72012681 TP1116

hydrocortisone spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70233-774
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	500 g in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
CITRONELLYL METHYLCROTONATE (UNII: K61O222P3D)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLIDOCANOL (UNII: 0AWH8BFG9A)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
MENTHYL ETHYLENE GLYCOL CARBONATE, (-)- (UNII: 4K3514B1GT)	
LACTIC ACID (UNII: 33X04XA5AT)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
MATRICARIA RECUTITA FLOWERING TOP (UNII: 3VNC7T6Z02)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70233-774-15	1 in 1 CARTON	06/01/2018	
1		15 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

### Marketing Information

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

**Labeler** - Fleet Laboratories LTD (217269489)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Fleet Laboratories LTD		217269489	manufacture(70233-774)

Revised: 6/2018

Fleet Laboratories LTD