ANTI-ITCH FEMININE CARE- hydrocortisone 0.5% cream
OHIO LAB PHARMA

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.

ACTIVE INGREDIENT

Hydrocortisone, USP 0.5%

PURPOSE

Anti-itch

USES

For temporary external feminine itching

WARNINGS

For External Use Only

Avoid Contact with eyes

DIRETIONS

Adults and children 12 years and older Apply to external vaginal area not more than 3 to 4 times a day
Children under 12 years Consult a doctor

DO NOT USE IF

you have a vaginal discharge. Consult a physician.

KEEP OUT OF REACH OF CHILDREN

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

OTHER INFORMATION

- store at 20°-25°C (68°-77°F)

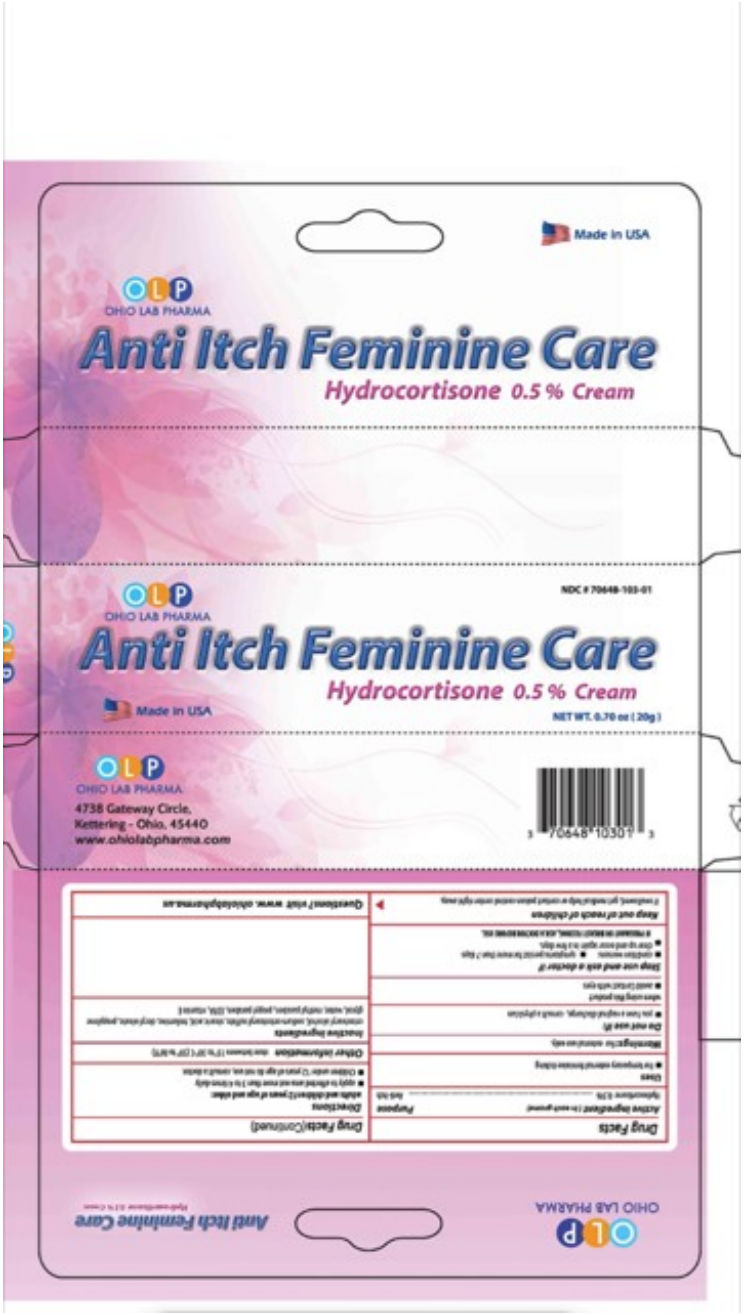
INACTIVE INGREDIENT

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

QUESTIONS

www.ohiolabpharma.us

PACKAGE LABEL



NET WT 1OZ (20G)

HYDROCORTISONE0.5%

ANTI-ITCH FEMININE CARE

hydrocortisone 0.5% cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70648-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70648-103-01	1 in 1 CARTON	02/01/2017	
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 not final	part348	02/01/2017	

Labeler - OHIO LAB PHARMA (080215854)

Registrant - OHIO LAB PHARMA (080215854)

Establishment

Name	Address	ID/FEI	Business Operations
OHIO LAB PHARMA		080215854	manufacture(70648-103)

Revised: 11/2018 OHIO LAB PHARMA