CVS FEMININE INTIMATE POWDER- miconazole nitrate powder PureTek Corporation

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.

Drug Facts

Active ingredient

Miconazole Nitrate 2%

Purposes

Antifungal

Uses

- for the treatment and relief of external genital itching
- relieves itching, scaling, cracking, burning, redness, soreness, irritation, discomfort and chafing associated with external genital itching

Warnings

For external use only

Do not use on children under 2 years of age unless directed by a doctor.

When using this product avoid contact with the eyes.

Stop use and ask a doctor if

• irritation occurs or if there is no improvement within 2 weeks

Keep out of reach of children.

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

Directions

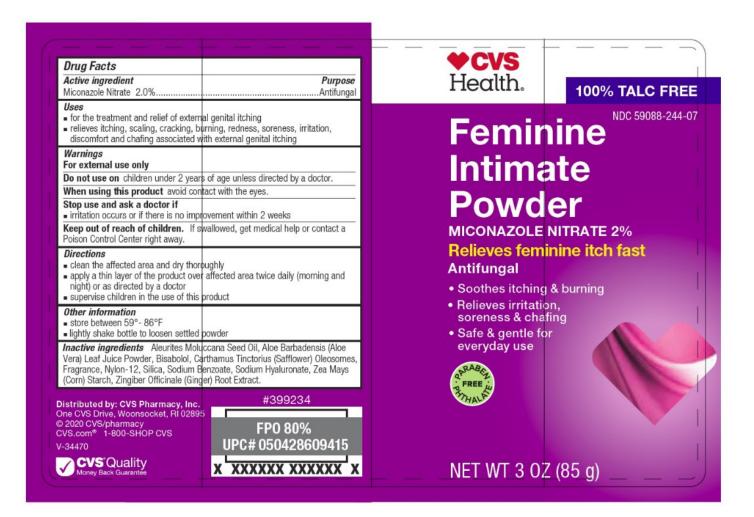
- clean the affected area and dry thoroughly
- apply a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor
- supervise children in the use of this product

Other information

- store between 59°-86°F
- lightly shake bottle to loosen settled powder

Inactive ingredients

Aleurites Moluccana Seed Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Bisabolol, Carthamus Tinctorius (Safflower) Oleosomes, Fragrance, Nylon-12, Silica, Sodium Benzoate, Sodium Hyaluronate, Zea Mays (Corn) Starch, Zingiber Officinale (Ginger) Root Extract.



CVS FEMININE INTIMATE POWDER

miconazole nitrate powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59088-244	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	20 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
KUKUI NUT OIL (UNII: TP11QR7B8R)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
LEVOMENOL (UNII: 24WE03BX2T)		
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)		
NYLON-12 (UNII: 446 U8 J0 75 B)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		

HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
STARCH, CORN (UNII: O8232NY3SJ)	
GINGER (UNII: C5529G5JPQ)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-244-07	85 g in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333C	05/31/2019		

Labeler - PureTek Corporation (785961046)

Establishment					
Name	Address	ID/FEI	Business Operations		
PureTek Corporation		785961046	manufacture(59088-244)		

Revised: 3/2020 PureTek Corporation