MICONAZOLE 7- miconazole nitrate cream TARGET Corporation

Miconazole 7

Drug Facts

Active ingredient

Miconazole Nitrate USP 2% (100 mg in each applicatorful)

Purpose

Vaginal antifungal

Use

- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal yeast infection

Warnings

For vaginal use only

Do not use if you have never had a vaginal yeast infection diagnosed by a doctor

Ask a doctor before use if you have

- vaginal itching and discomfort for the first time
- lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS

Ask a doctor or pharmacist before use if you are taking the prescription blood thinning medicine warfarin, because bleeding or bruising may occur

When using this product

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs)
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief ask a doctor before using another product

Stop use and ask a doctor if

- symptoms do not get better in 3 days
- symptoms last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting or foul-smelling vaginal discharge

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- before using this product, read the enclosed consumer information leaflet for complete directions and information
- adults and children 12 years of age and over:
 - **applicators:** insert 1 applicatorful into the vagina at bedtime for 7 nights in a row. Throw away applicator after each use.
 - use the same tube of cream if you have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina (vulva). Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor

Other information

- do not purchase if carton is opened
- do not use if seal over tube opening has been punctured or is not visible

To open: unscrew cap, use pointed end on cap to puncture seal

To close: screw cap back onto the tube

- store at 20°-25°C (68°-77°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

Apricot Kernel Oil/PEG-6, Butylated Hydroxytoluene, Mineral Oil, PEG-6-32 Stearate/Glycol Stearate, Purified Water and Benzoic Acid (0.20%) as a preservative

Questions?

Call 1-800-910-6874

Distributed by Target Corporation Minneapolis, MN 55403

PRINCIPAL DISPLAY PANEL - 45 g Tube Carton

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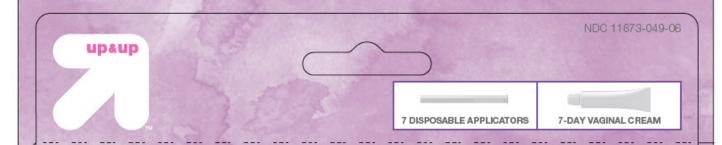
NDC 11673-049-06

7 DISPOSABLE APPLICATORS 7-DAY VAGINAL CREAM

Compare to active ingredient in Monistat® 7*

7-day treatment miconazole 7 miconazole nitrate vaginal cream USP (2%) (miconazole nitrate 100 mg per application)

vaginal antifungal cures most vaginal yeast infections and relieves associated external itching and irritation 7-day vaginal cream with disposable applicators educational brochure enclosed NET WT 1.5 OZ (45 g) TUBE + 7 DISPOSABLE APPLICATORS



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Compare to active ingredient in Monistat® 7*

7-day treatment

miconazole 7

miconazole nitrate vaginal cream USP (2%) (miconazole nitrate 100 mg per application)



vaginal antifungal

cures most vaginal yeast infections and relieves associated external itching and irritation

7-day vaginal cream with disposable applicators educational brochure enclosed

NET WT 1.5 OZ (45 g) TUBE + 7 DISPOSABLE APPLICATORS



100% satisfaction guaranteed or your money back.

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*This product is not manufactured or distributed by Insight Pharmaceutical LLC owner of the registered trademark Monistat® 7.



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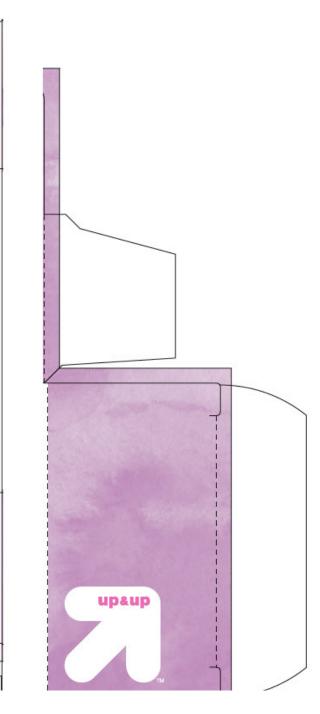
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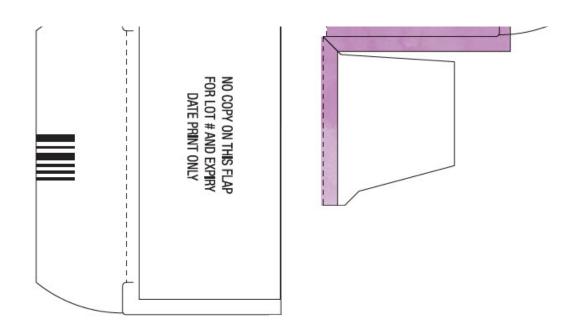
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Drug Facts (continued)



LPK-9152-0 1119-0 68



MICONAZOLE 7

miconazole nitrate cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-049	
Route of Administration	VAGINAL			

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	
Butylated Hydroxytoluene (UNII: 1P9 D0 Z171K)		
Mineral Oil (UNII: T5L8T28FGP)		
Water (UNII: 059QF0KO0R)		
Benzoic Acid (UNII: 8 SKN0 B0 MIM)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-049- 06	1 in 1 CARTON	11/25/2019	
1		45 g in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA074444	0 1/13/19 9 7		

Labeler - TARGET Corporation (006961700)

Revised: 11/2019 TARGET Corporation