

MONISTAT 7 7-DAY DISPOSABLE APPLICATORS- miconazole nitrate cream
Insight Pharmaceuticals LLC

Monistat 7 Simply - 7 dispos apps-Cream

Drug Facts

Active ingredient

Purpose

Miconazole nitrate 2%Vaginal antifungal

Uses

- 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 applicator away after 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 the cream onto the itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor.

Other information

- do not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F)

Inactive ingredients

benzoic acid, cetyl alcohol, isopropyl myristate, polysorbate 60, potassium hydroxide, propylene glycol, purified water, stearyl alcohol

Questions?

If you have any questions or comments, please call 1-877-666-4782

PRINCIPAL DISPLAY PANEL

MONISTAT® 7
Miconazole Nitrate Vaginal Cream (2%)

Vaginal Antifungal

Net Wt. 1.59 oz. (45g) Tube + 7 Disposable Applicators

MONISTAT[®] 7

Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

**TAMPER-EVIDENT
UNIT DO NOT USE
IF SEAL OVER
TUBE HAS BEEN
PUNCTURED.**

MONISTAT[®] 7

Miconazole Nitrate Vaginal Cream (2%) – Vaginal Antifungal

- ✓ CURES most vaginal YEAST INFECTIONS
- ✓ Relieves associated external itching and irritation

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Drug Facts (continued)

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miconazole nitrate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-026
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
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-026-15	7 in 1 CARTON	04/26/1993	
1		45 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017450	04/26/1993	

Labeler - Insight Pharmaceuticals LLC (055665422)