

**MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS-
miconazole nitrate
Insight Pharmaceuticals LLC**

Monistat 7 Cure Itch Relief - PreFilledApps-Cream

**MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS-
miconazole nitrate
Insight Pharmaceuticals**

MONISTAT® 7 Combination Pack

Drug Facts

Active ingredient

Miconazole nitrate 2%

Miconazole nitrate 2% (external cream)

Purpose

Vaginal antifungal

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 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 disease (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 use.
 - **external cream:** 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 not use if seal over tube opening has been punctured
- do not purchase if carton is open
- store at 20° - 25°C (68° to 77°F)
- Keep this carton for future reference. It contains s=water,steoryl adkkctklh

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 - Kit Carton

MONISTAT® 7

COMBINATION PACK

Miconazole Nitrate Vaginal Cream (2%) VAGINAL ANTIFUNGAL

Cream with 7 Disposable Applicators plus External Cream for Itch Relief

Net Wt. 1.59 oz (45 g) Tube + 0.32 oz (9 g) Tube + 7 Disposable Applicators



MONISTAT 7 COMBINATION PACK 7-DAY PRE-FILLED APPLICATORS

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-023
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-023-15	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	04/26/1993	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	7 TUBE, WTH APPLICATOR	35 g
Part 2	1 TUBE	9 g

Part 1 of 2

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

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		5 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	

Part 2 of 2

MICONAZOLE NITRATE

miconazole nitrate cream

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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		9 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
NDA	NDA017450	04/26/1993	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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