

MICONAZOLE 3- miconazole nitrate
CVS Pharmacy

Miconazole 3 Complete Pack Kit

Active ingredients

Miconazole nitrate (200 mg in each vaginal insert)

Purpose

Vaginal antifungal

Active ingredients

Miconazole nitrate 2% (external cream)

Purpose

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:
 - **vaginal insert:** with a disposable applicator place the insert into the vagina at bedtime. 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 (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 use if **printed** sealed pouches containing vaginal inserts are torn, open, or incompletely sealed
- 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

vaginal insert: gelatin, glycerin, hydrogenated vegetable oil base, titanium dioxide

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

Questions? call toll-free 1-855-590-5695

PRINCIPAL DISPLAY PANEL

Compare to the active ingredients of Monistat[®] 3

3-Day Treatment; 3-Step System

Yeast Infection Relief

Miconazole 3

MICONAZOLE NITRATE VAGINAL INSERTS (200 mg)

MICONAZOLE NITRATE CREAM (2%)

Vaginal Antifungal Combination Pack

- Cures most vaginal yeast infections
- Relieves associated external itching & irritation

3 VAGINAL SOFTGEL INSERTS, 3 APPLICATORS, 1 EXTERNAL CREAM, 4 FEMININE WIPES
 NET WT 3 VAGINAL SOFTGEL INSERTS + 0.32 OZ (9 g) TUBE



MICONAZOLE 3
 miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-950
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-950-01	1 in 1 PACKAGE, COMBINATION; Type 1: Convenience Kit of Co-Package	04/16/1996	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	3 APPLICATOR	3
Part 2	1 TUBE	9 g

Part 1 of 2**MICONAZOLE NITRATE**

miconazole nitrate insert

Product Information

Route of Administration	VAGINAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
CORN OIL (UNII: 8470G57WFM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	04/16/1996	

Part 2 of 2

MICONAZOLE NITRATE

miconazole nitrate cream

Product Information

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 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: 2KR89I4HIY)	

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	NDA020670	04/16/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	04/16/1996	

Labeler - CVS Pharmacy (062312574)

Registrant - Insight Pharmaceuticals (078774214)

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