MICONAZOLE 1 WALGREENS- miconazole nitrate
WALGREEN COMPANY

Miconazole 1 Combination Pack

Drug Facts

Active ingredients

Miconazole nitrate 1200 mg (in vaginal insert)

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 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 the applicator, place the vaginal insert into the vagina. Throw applicator away 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 pouch is 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)
- this is a 1-dose treatment. Most women do not get complete relief of their symptoms in just 1 day. Most women get some improvement in 1 day and complete relief by 7 days.

Inactive ingredients

vaginal insert: gelatin, glycerin, lecithin, mineral oil, titanium dioxide, white petrolatum

external cream: 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

Miconazole
Miconazole Nitrate Vaginal Insert (1200 mg)

Miconazole Nitrate Cream (2%)

VAGINAL ANTIFUNGAL | 1-DAY TREATMENT

Net Wt. 0.32oz (9g) tube & 1 OVULE Insert

Walgreens

1 Vaginal Softgel Insert With 1 Flexible Applicator

Cream for External Relief

Miconazole

1

COMBINATION PACK
MICONAZOLE NITRATE VAGINAL INSERT (1200 mg)
MICONAZOLE NITRATE CREAM (2%)

VAGINAL ANTIFUNGAL | 1-DAY TREATMENT

Walgreens

Compare to Monistat® 1 Combination Pack active ingredients*

NDC [illegible]

Miconazole

1

COMBINATION PACK
MICONAZOLE NITRATE VAGINAL INSERT (1200 mg)
MICONAZOLE NITRATE CREAM (2%)

VAGINAL ANTIFUNGAL | 1-DAY TREATMENT

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

1 OVULE INSERT
CREAM FOR EXTERNAL RELIEF

NET WT 0.32 OZ (9 g) TUBE & 1 OVULE INSERT

Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey
*This product is not manufactured or distributed by
INSIGHT Pharmaceuticals LLC, owner of the registered trademark Monistat®

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

Walgreens 100% SATISFACTION GUARANTEED

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LOT/EXP AREA

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

Drug Facts

Active ingredients	**Purpose**
Miconazole nitrate 1200 mg (in vaginal insert)	Vaginal antifungal
Miconazole nitrate 2% (external cream)	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,**

▶

Drug Facts (continued)

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
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- children under 12 years of age: ask a doctor

Other information
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- **external cream:** 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-[illegible]

MICONAZOLE 1 WALGREENS

miconazole nitrate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-5201

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-5201-01	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	11/30/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 POUCH	1
Part 2	1 TUBE	9 g

Part 1 of 2

MICONAZOLE NITRATE

miconazole nitrate suppository

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	1200 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Mineral Oil (UNII: T5L8T28FGP)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item	Package Description	Marketing Start	Marketing End

#	Code	Package Description	Date	Date
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	11/30/2021	

Part 2 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		9 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
NDA	NDA021308	11/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	11/30/2021	

Labeler - WALGREEN COMPANY (008965063)

Registrant - Insight Pharmaceuticals (055665422)

Revised: 8/2021

WALGREEN COMPANY