# MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS- miconazole nitrate Insight Pharmaceuticals LLC

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## MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS

## **Drug Facts**

## **Active ingredients**

Miconazole nitrate (200 mg in each 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 a disposable applicator, place the insert into the vagina at bedtime. 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. 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?

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

## PRINCIPAL DISPLAY PANEL

## MONISTAT® 3 COMBINATION PACK

Miconazole Nitrate Vaginal Inserts (200 mg) and Miconazole Nitrate Vaginal Cream (2%)

VAGINAL ANTIFUNGAL

**3 OVULE**<sup>®</sup> **Inserts** with 3 Applicators (Net Wt. 3 OVULE<sup>®</sup> Inserts)

plus External Cream for Itch Relief (0.32 oz (9 g) Tube

Ovule<sup>®</sup>

Plus External Cream for Itch Relief

VAGINAL ANTIFUNGAL

if you have any questions or omments, please call 1-877-MONISTAT (1-877-666-4782)

Miconazole Nitrate Vaginal Inserts (200 mg) and Miconazole Nitrate Vaginal Cream (2%) VAGINAL ANTIFUNGAL

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

3 Ovule® Inserts

3 OVULE® Inserts with 3 Applicators plus External Cream for Itch Relief

Net Wt. 3 OVULE\* Inserts + 0,32 oz (9g) Tube

If you have any

questions or comments, please call

1-877-MONESTAT (1-877-666-4782)

TAMPER-EVIDENT UNIT DO NOT USE IF PRINTED SEALED POUCHES ARE TORN, OPEN OR INCOMPLETELY SEALED.

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## MONISTAT 3 COMBINATION PACK 3 OVULE INSERTS

miconazole nitrate kit

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63736-019

## **Packaging**

# Item C		age Description	Marketing Start Date	Marketing End Date
1 NDC:63736	-019 - 1 in 1 PACKAGE, COMBII Product	JATION; Type 0: Not a Combination	04/16/1996	

## **Quantity of Parts**

A	010, 01 1 01 05	
Part #	Package Quantity	Total Product Quantity
Part 1	1 KIT	3
Part 2	1 TUBE	9 g

## Part 1 of 2

## **MICONAZOLE NITRATE**

miconazole nitrate suppository

## **Product Information**

Route of Administration VAGINAL

## Active Ingredient/Active Moietv

- O	<b>5</b>		
	Ingredient Name	Basis of Strength	Strength
Miconazole Nitrate (UN	II: VW4H1CYW1K) (Miconazole - UNII:7NNO0D7S5M)	Miconazole Nitrate	200 mg

# Inactive Ingredients Ingredient Name Strength Gelatin (UNII: 2G86QN327L) Glycerin (UNII: PDC6A3C0OX) Titanium Dioxide (UNII: 15FIX9V2JP)

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1		3 in 1 KIT; Type 1: Convenience Kit of Co-Package		
		, , , , ,		

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 VAGINAL

## Active Ingredient/Active Moiety

9	J			
	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: 0 RE8 K4LNJS)		
Polysorbate 60 (UNII: CAL22UVI4M)		
Potassium Hydroxide (UNII: WZH3C48M4T)		
Propylene Glycol (UNII: 6DC9Q167V3)		
Water (UNII: 059QF0KO0R)		
Stearyl Alcohol (UNII: 2KR89I4H1Y)		

I	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1		9 g in 1 TUBE; Type 0: Not a Combination Product		

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

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

NDA NDA020670 04/16/1996

## Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 2/2019 Insight Pharmaceuticals LLC