MONISTAT 1 COMBINATION PACK- miconazole nitrate
Insight Pharmaceuticals LLC

MONISTAT 1 COMBINATION PACK - Cure Itch Relief

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, 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 or sealed vaginal insert blister 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?

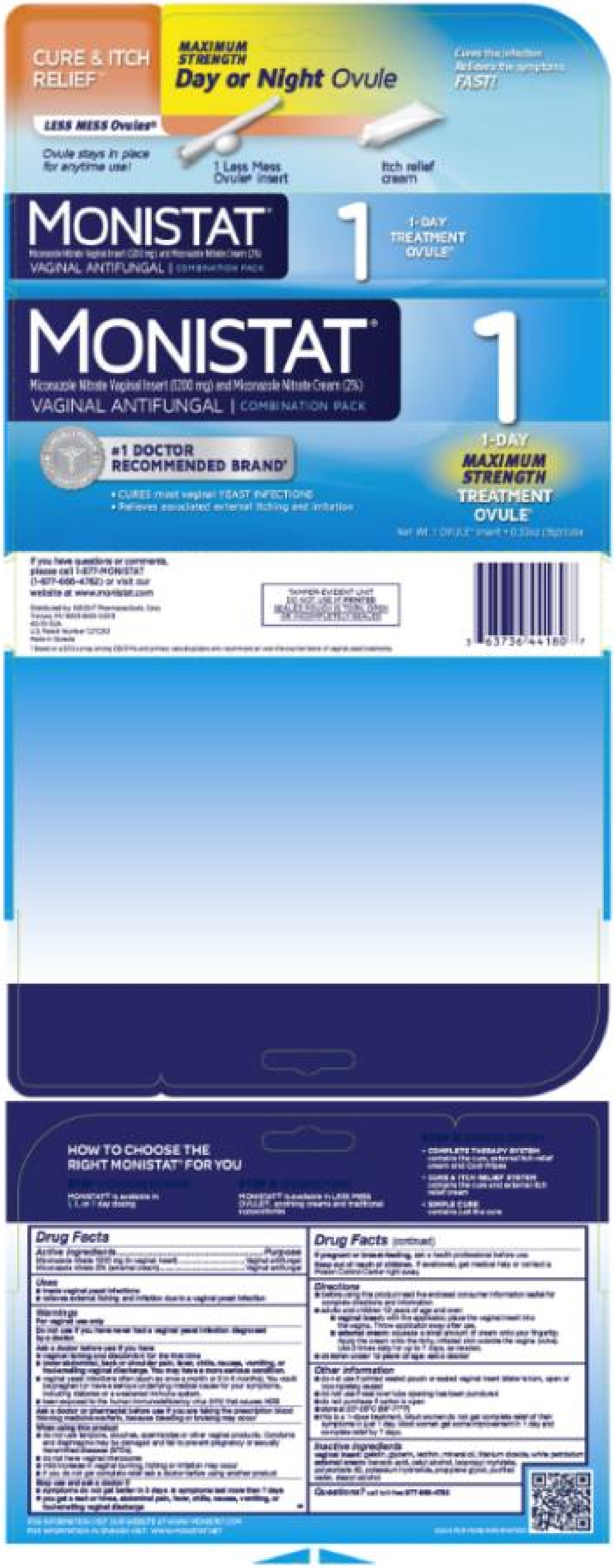
call toll-free **877-666-4782**

PRINCIPAL DISPLAY PANEL

Kit Carton

MONISTAT®
Miconazole Nitrate Vaginal Insert (1200 mg) and Miconazole Nitrate Cream (2%)
VAGINAL ANTIFUNGAL | COMBINATION PACK

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


CURE & ITCH RELIEF
MAXIMUM STRENGTH
Day or Night Ovule
Cures the infection
Relieves the symptoms
FAST!
LESS MESS Ovules®
Ovule stays in place for anytime use!
1 Less Mess Ovule® insert
Itch relief cream
MONISTAT
VAGINAL ANTIFUNGAL | COMBINATION PACK
1
1-DAY TREATMENT OVULE®
MONISTAT®
Miconazole Nitrate Vaginal Insert (1200 mg) and Miconazole Nitrate Cream (2%)
VAGINAL ANTIFUNGAL | COMBINATION PACK
1
#1 DOCTOR RECOMMENDED BRAND†
1-DAY
MAXIMUM STRENGTH
TREATMENT OVULE®
If you have questions or comments, please call 1-877-MONISTAT (1-877-666-4782) or visit our website at www.monistat.com
HOW TO CHOOSE THE RIGHT MONISTAT® FOR YOU
Drug Facts
Drug Facts (continued)
Active ingredients
Purpose
Uses
Warnings
For vaginal use only
Directions
Other information
Inactive ingredients
Questions?

MONISTAT 1 COMBINATION PACK

miconazole nitrate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63736-013

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63736-013-30	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	06/29/2001	

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 Code**	**Package Description**	**Marketing Start Date**	**Marketing End 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	06/29/2001	

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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	06/29/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021308	06/29/2001	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 2/2020 Insight Pharmaceuticals LLC