MONISTAT 3 COMBINATION PACK- miconazole nitrate
Insight Pharmaceuticals

MONISTAT® 3
COMBINATION PACK

Miconazole Nitrate Vaginal Suppositories (200 mg) and Miconazole Nitrate Vaginal Cream (2%)
Vaginal Antifungal

DRUG FACTS

Active ingredients	*Purpose*
Miconazole nitrate (200 mg in each suppository)	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:
- **suppositories:** insert 1 suppository into the vagina at bedtime for 3 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 printed suppository blister is torn, open or incompletely sealed
- do not use if seal over tube opening has been punctured or embossed design ⛉ is not visible
- do not purchase if carton is open
- store at 20°-25°C (68°-77°F)

Inactive ingredients

suppository: hydrogenated vegetable oil base

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
Visit our website @ www.monistat.com

PRINCIPAL DISPLAY PANEL - Kit Carton

3 DAY TREATMENT • CREAM

MONISTAT® 3
Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Cream (2%)
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)
VAGINAL ANTIFUNGAL

CLINICALLY PROVEN
MULTI-SYMPTOM RELIEF

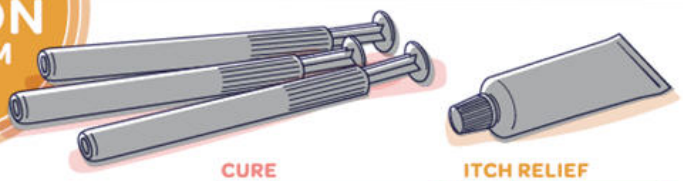
CURES MOST VAGINAL YEAST INFECTIONS
and relieves associated external itching and irritation

COMBINATION PACK

Net Wt. 0.18 oz. (5g) each applicator • 0.32 oz. (9g) tube

DUAL ACTION SYSTEM

CURES THE INFECTION
RELIEVES THE SYMPTOMS



CURE
1 3 pre-filled cream applicators

ITCH RELIEF
2 soothing itch relief cream

MONISTAT® 3

Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Cream (2%)
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)

VAGINAL ANTIFUNGAL

COMBINATION PACK

3 DAY TREATMENT • CREAM

MONISTAT® 3

Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Cream (2%)
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)

VAGINAL ANTIFUNGAL

CLINICALLY PROVEN MULTI-SYMPTOM RELIEF

CURES MOST VAGINAL YEAST INFECTIONS
and relieves associated external itching and irritation

COMBINATION PACK

Net Wt. 0.18 oz. (5g) each applicator • 0.32 oz. (9g) tube

EXPIRATION DATE
LOT #

NON-VARNISH AREA

MONISTAT® 3
Miconazole Nitrate Vaginal Cream (4%) and Miconazole Nitrate Cream (2%)
(Miconazole Nitrate 200 mg per applicator plus 2% external vulvar cream)
VAGINAL ANTIFUNGAL

OPEN HERE

If you have questions or comments, call toll-free 877-MONISTAT or 215-273-8755 (collect) or visit our website at www.monistat.com

Distributed by: INSIGHT Pharmaceuticals, LLC.
Langhorne, PA 19047-1749

40-72-110A 280203

U.S. Patent No. 7,104,968. Other patents pending.
Made in Belgium.

TAMPER-EVIDENT UNIT
DO NOT USE IF PRINTED APPLICATOR WRAPPER IS TORN, OPEN OR INCOMPLETELY SEALED

FPO

3 63736 44300 9

VISIT OUR WEBSITE AT WWW.MONISTAT.COM

Drug Facts

Active ingredients	Purpose
Miconazole nitrate 4% (200 mg in each applicator)	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. (HIV) that causes AIDS
- been exposed to the human immunodeficiency virus

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
- real 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
- symptom is last more than 7 days
- you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge

SCAN FOR MORE INFORMATION

Questions? call toll-free 877-668-4782 or 215-273-8755 (collect)

Inactive ingredients

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

Other information

- do not use if printed wrapper 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)

Drug Facts (continued)

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 applicator full into the vagina at bedtime for 3 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 (vulva). Use 2 times daily for up to 7 days, as needed.
- children under 12 years of age: ask a doctor

Varnish Free Area 280203

FPO

Varnish Free Area 280203

FPO

COMBINATION PACK

MONISTAT 3 COMBINATION PACK

miconazole nitrate kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63736-018

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63736-018-03	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	3
Part 2	1 TUBE	9 g

Part 1 of 2

MONISTAT 3

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	200 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		3 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	12/10/2009	

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	10 mg in 0.5 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	12/10/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020670	12/10/2009	

Labeler - Insight Pharmaceuticals (176792315)

Establishment

Name	Address	ID/FEI	Business Operations
Jubilant		246762764	MANUFACTURE(63736-018)

Revised: 8/2012 Insight Pharmaceuticals