

TERRASIL RAPID-RELIEF VAGINAL- miconazole nitrate
Aidance Skincare & Topical Solutions, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Miconazole Nitrate 2%

Purpose

Vaginal Antifungal

Uses

Treats vaginal yeast infections.

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 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 disease (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 after 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

Children under 12: Ask a doctor.

Adults and children 12 years and over:

Ointment: May be used topically (outside the vaginal area) or intravaginally.

Squeeze a small amount of ointment onto fingertip.

Apply 2-3 times daily for up to 3 days or longer, as needed. May stain fabrics.

Cleansing Bar: Wash affected area daily. Store at room temperature.

Inactive Ingredients

Ointment: beeswax (organic), bentonite (volcanic clay), jojoba seed oil, magnesium oxide, peppermint oil, sage oil, silver oxide, tea tree oil, zinc oxide.

Cleansing Bar: beeswax, bentonite clay, coconut oil, glycerin, jojoba seed oil, lauric acid, lavender oil, magnesium oxide, olive oil, palm acid, palm kernel acid, pentasodium pentetate, peppermint oil, propylene glycol, purified water, silver oxide, sodium stearate, sorbitol, shea butter, sodium laureth sulphate (SLES), stearic acid, sodium chloride, sodium palmate, sodium palm kernelate, sorbitol, tea tree oil, titanium dioxide, tetrasodium etidronate, zinc oxide.

PRINCIPAL DISPLAY PANEL - BOX

Vaginal Discomfort

- Vaginal Itch
- Odor and Discharge
- Yeast Infection and Vaginitis

All Natural

terrasil

RAPID-RELIEF VAGINAL OINTMENT

Plus Medicated Cleansing Bar

2.5X FASTER

*compared to leading brands
in scientific studies*

THE END OF SUFFERING

Healing and Relief Since 2004



Patented system targets infection and speeds healing

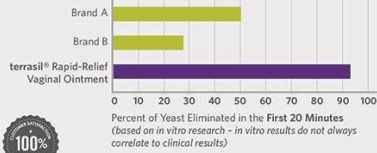
RAPID-RELIEF VAGINAL OINTMENT

Welcome to the End of Suffering Skin.[™]
Relief and healing starts today.

Our positively-charged Activated Minerals[®] target the negatively-charged microbes causing most skin problems. This technology was developed to speed delivery of the active ingredients and is why customers worldwide experience such fast relief and healing. **EASY TO USE**



terrasi[®] Rapid-Relief Vaginal Ointment has more than 2.5X (on average) the yeast-fighting power of other products



Use our products risk-free for 90 days.
Questions? 401-432-7750 or www.aidance.com



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TERRASIL[®] RAPID-RELIEF VAGINAL OINTMENT



RAPID-RELIEF VAGINAL OINTMENT

Drug Facts

Active ingredient

Miconazole Nitrate 2%

Purpose

Vaginal Antifungal (Ointment and Cleansing Bar)

Uses

Treats vaginal yeast infections.

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.
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• 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

Vaginal Discomfort



- Vaginal Itch
- Odor and Discharge
- Yeast Infection and Vaginitis



THE END OF SUFFERING
Healing and Relief Since 2004

FDA Registered Net WT 25g (0.9oz) Tube + 1 Cleansing Bar

RAPID-RELIEF VAGINAL OINTMENT

Drug Facts (continued)

Stop use and ask a doctor if
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• symptoms last more than 7 days
• you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge.
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Inactive ingredients
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TERRASIL RAPID-RELIEF VAGINAL

miconazole nitrate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-162
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-162-25	1 in 1 PACKAGE, COMBINATION		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	25 g
Part 2	1 CARTON	75 g

Part 1 of 2

TERRASIL RAPID-RELIEF VAGINAL

miconazole nitrate ointment

Product Information

Item Code (Source)	NDC:24909-172
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SAGE OIL (UNII: U27K0H1H2O)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-172-25	25 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/18/2014	

Part 2 of 2

TERRASIL MEDICATED VAGINAL CLEANSING BAR

miconazole nitrate soap

Product Information

Item Code (Source)	NDC:24909-182
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MICONAZOLE NITRATE (UNII: VW4HICYW1K) (MICONAZOLE - UNII:7NNO0D7S5M)	MICONAZOLE NITRATE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLYCERIN (UNII: PDC6A3C0OX)	
JOJOBA OIL (UNII: 724GKU717M)	
LAURIC ACID (UNII: 1160N9NU9U)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PALM ACID (UNII: B6G0Y5Z616)	
PALM KERNEL ACID (UNII: 79P21R4317)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILVER OXIDE (UNII: 897WUN6G6T)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SHEA BUTTER (UNII: K49155WL9Y)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
SORBITOL (UNII: 506T60A25R)	
TEA TREE OIL (UNII: VIF565UC2G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		75 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	04/18/2014	

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-162) , label(24909-162)

Revised: 4/2014

Aidance Skincare & Topical Solutions, LLC