**VAGISTEN-V 7 DAY- miconazole nitrate cream**
**OPMX 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.*

---

**ACTIVE INGREDIENTS**

MICONOZOLE NITRATE 2% (100 MG IN EACH APPLICATOR)

**PURPOSE**

VAGINAL ANTIFUNGAL

**USES**

- TREATS VAGINAL YEAST INFECTIONS
- RELIEVES EXTERNAL ITCHING AND URINATION DUE TO 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 FIRST TIME
- LOWER ABDOMINAL, BACK OR SHOULDER PAIN, FEVER, CHILLS, NASEA, 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 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 HAVE TAKEN A PRESCRIPTION BLOOD THINNING MEDICINE, SUCH AS WARFARIN, BECAUSE BLEEDING OR BRUISING MAY OCCUR.

WHEN USING THIS PRODUCT

- DO NOT USE TAMPONS, DOUCHES, SPERMACIDES OR OTHER VAGINAL PRODUCTS. CONDOMS AND DIAPHRAGMS MAY BE DAMAGED OR FAIL TO PREVENT PREGNANCY OR SEXUALLY TRANSMITTED DISEASES (STDS).
- DO NOT HAVE VAGINAL INTERCOURSE
- MILD INCREASE IN VAGINAL BURNING, ITCHING OR IRRITATION MAY OCCUR.

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 HIVESS, ABDOMINAL PAIN, FEVER, CHILLS, NAUSEA, VOMITING

OR FOUL-SMELLING 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 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 OR OVER:
- APPLICATOR: INSERT 1 APPLICATOR INTO THE VAGINA AT BEDTIME FOR 7 NIGHTS IN A ROW. THROW APPLICATOR AWAY AFTER USE.
- EXTERNAL CREAM: USE THE SAME TUBE OF CREAM IF YOU HAVE ITCHING AND IRRITATION ON THE SKIN OUTSIDE THE VAGINA. SQUEEZE A SMALL AMOUNT OF CREAM ONTO YOUR FINGERTIP. APPLY TO 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.

**INACTIVE INGREDIENTS**

BENZOIC ACID, BUTYLATED HYDROXYANISOLE, GLYCERINE STEARATE, MINERAL OIL, PEGLICOL 5 OLEATE, PEGOXOL 7 STEARATE, PURIFIED WATER

**OTHER INFORMATION**

- DO NOT USE IF SEAL TUBE OPENING HAS BEEN PUNCTURED
- DO NOT PURCHASE IF CARTON OPEN
- STORE AT 20° - 25°C (68°F - 77°F)

# Vagisten-V

**Miconazole Nitrate** 100 mg per applicator
**Vaginal Cream 2%**
**Antifungal / Antimicótico**

8 56828 00821 2

NDC 69729-612-05

# Vagisten-V

7 DAY Vaginal Treatment

**Miconazole Nitrate** 100 mg per applicator
**Vaginal Cream 2%**
**Antifungal / Antimicótico**

**Cures Most Vaginal Yeast Infections**
**Relieves Associated External Itching and Irritation**

Eficaz tratamiento contra infecciones vaginales
Alivia el picor externo y la irritación

**Net Wt.**
**0.5 oz. (14g)**

Made for:
inov FARMACEUTIQUE
San Diego, CA

Exclusively distributed by:
OPMX
San Diego, CA 92154
**Phone: 619-600-5632**

MADE IN INDIA

## Drug Facts

***Active ingredient*** ***Purpose***
Miconazole nitrate 2% (100 mg in each applicator).....Vaginal antifungal

***Uses***
- treats vaginal yeast infections
- relieves external itching and uritation 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 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 have** taking a prescription blood thinning medicine, such as warfarin, beacause bleeding or bruising may occur

**When using this product**
- do not use tampons, douches, spermicides cr other vaginal products. Condoms and daghrepms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs). ▪ do not have vaginal intercouse
- mild increase in vaginal burning, itching or irritation may occur

## Drug Facts (continued)

**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, fevor, chills, nausea, vomlting or foul-smelling discharge**

**If pregnant or breastdeeding**, ask a health professional before use.
**Keep out of reach of children.** I swallowed, get medical help or contact a Poison Control Center right away.

***Directions*** ▪ before using this product read the enclosed consumer information leafle for complete drections and information
- adults and children 12 years of age and over:
  - **applicator:** insert 1 applicator into the vagina at bedtime for 7 nights in a row. Throw applicator away after use
  - **external cream:** use the same tube of cream if vou have itching and irritation on the skin outside the vagina. Squeeze a small amount of cream onto your fingertip. Apply to 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

***Inactive ingredient***
benzoic acid, butylated hydroxyaniscle, glycerine stearate, mineral oil, peglicol 5 oleate, pegoxol 7 stearate, purified water

***Other information***
- do not use if seal tube opening has been punctured
- do not purchase if carton open ▪ store at 20°-25°C (68°-77°F)

**VAGISTEN-V 7 DAY**

miconazole nitrate cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69729-612 |
| **Route of Administration** | VAGINAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MICONAZOLE NITRATE** (UNII: VW4H1CYW1K) (MICONAZOLE - UNII:7NNO0D7S5M) | MICONAZOLE NITRATE | 2 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **BUTYLATED HYDROXYANISOLE** (UNII: REK4960K2U) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **PEG-5 OLEATE** (UNII: 0240V77G50) | |
| **PEGOXOL 7 STEARATE** (UNII: 3EW5AXE5X5) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:69729-612-05 | 1 in 1 BOX | 09/05/2018 | |
| **1** | NDC:69729-612-01 | 14 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 |
|---|---|---|---|
| OTC monograph final | part333C | 09/05/2018 | |

## Labeler - OPMX LLC (029918743)

Revised: 9/2018 OPMX LLC