

CLOTRIMAZOLE- clotrimazole cream

A-S Medication Solutions

Clotrimazole Vaginal Cream USP 1%

Drug Facts

| <i>Active ingredients</i> | <i>Purpose</i> |
|---|-----------------------|
| Clotrimazole USP 1% (50 mg in each applicatorful) | Vaginal antifungal |
| Clotrimazole USP 1% (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

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 a 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 educational brochure for complete directions and information
- adults and children 12 years of age and over:
 - **vaginal cream:** insert one applicatorful of cream into the vagina at bedtime for 7 days in a row. Wash applicator after each 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. Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor

Other information

- To open: unscrew cap, use pointed end on cap to puncture seal
- do not use if carton is opened
- **safety sealed:** the tube opening should be sealed. If the seal has been punctured or is not visible, do not use the product.
- store between 20° to 25°C (68° to 77°F)
- see flap of carton or crimp of tube for lot number and expiration date

Inactive ingredients

2-octyldodecanol, benzyl alcohol, cetostearyl alcohol, cetyl esters wax, polysorbate 60, purified water, sorbitan monostearate

Questions or comments?

call **1-866-923-4914**

Distributed by:

Ohm Laboratories Inc.

New Brunswick, NJ 08901

Made in Canada

HOW SUPPLIED

Product: 50090-0614

NDC: 50090-0614-0 45 g in a TUBE / 1 in a CARTON

Clotrimazole

NDC 50090-0614-0
A-S Medication Solutions, LLC
Product No. 4546-0
LOT

CLOTRIMAZOLE
7 DAY VAGINAL CREAM, USP
(1%)

VAGINAL ANTIFUNGAL

ACTIVE INGREDIENTS: CLOTRIMAZOLE USP

1% (50 MG IN EACH APPLICATORFUL)

CLOTRIMAZOLE USP 1% (EXTERNAL CREAM)

STORE AT 68 TO 77 DEGREES F

ONE 45G (1.5 OZ) TUBE OF

CLOTRIMAZOLE VAGINAL

CREAM (1%) & 1 REUSABLE

APPLICATOR



GTIN: 00350090061406

LOT:

EXP:

S/N:

DISTRIBUTED BY:

A-S Medication Solutions

Libertyville, IL 60048

SOURCE NDC: 51672-2003-6

CLOTRIMAZOLE

clotrimazole cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|--------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50090-0614(NDC:51672-2003) |
| Route of Administration | VAGINAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65) | CLOTRIMAZOLE | 1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| CETEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETYL ESTERS (UNII: D072FFP9GU) | |
| OCTYLDODECANOL (UNII: 461N1O614Y) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| AQUA (UNII: 059QF0KOOR) | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:50090-0614-0 | 1 in 1 CARTON | 11/28/2014 | |
| 1 | | 45 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 |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA072641 | 12/04/1995 | |

Labeler - A-S Medication Solutions (830016429)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---------------------|
| A-S Medication Solutions | | 830016429 | RELABEL(50090-0614) |

Revised: 1/2026

A-S Medication Solutions