

CLOTRIMAZOLE- clotrimazole cream
Strategic Sourcing Services LLC

Clotrimazole Vaginal Cream, USP

Drug Facts

Active ingredients

Clotrimazole, USP 1% (50 mg in each applicatorful)

Active ingredients

Clotrimazole, USP 1% (external cream)

Purpose

Vaginal antifungal

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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 (1-800-222-1222) 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 tube: unscrew cap, lift tab, and pull to remove foil seal prior to use
- do not use if foil seal on tube opening is broken or missing
- do not purchase if carton is open
- store at room temperature 20° to 25°C(68° to 77°F)
- before using any medication, read all label directions, Keep carton, it contains important information.

Inactive ingredients

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

Questions?

Call 1-**833-358-6431** Monday to Friday 9am to 7pm EST

Principal display panel

clotrimazole

Vaginal Cream, USP 1% • Vaginal Antifungal (with 1 Reusable Applicator)

Cures most vaginal yeast infections

7-day therapy / 7- day treatment

One 1.59 OZ (45g) TUBE OF VAGINAL CREAM (1%)

AND 1 REUSABLE PLASTIC APPLICATOR (7-DAY THERAPY

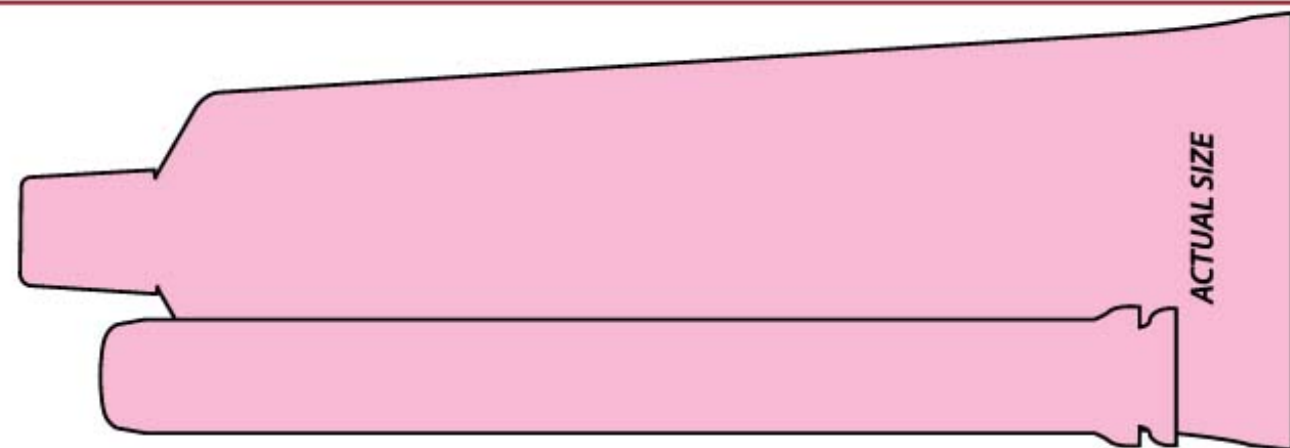
Distributed by McKesson Corp.,

via Strategic Sourcing Services LLC,

Memphis, TN 38141

www.sunmarkbrand.com

Package label



NDC 49348-793-76

clotrimazole

Vaginal Cream, USP 1% • Vaginal Antifungal (with 1 Reusable Applicator)

Cures most vaginal yeast infections
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EDUCATIONAL PAMPHLET ENCLOSED

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<p>Drug Facts</p> <p>Active Ingredients Clotrimazole, USP 1% (50 mg in each applicator) Clotrimazole, USP 1% (external cream) Vaginal antifungal</p> <p>Purpose Vaginal antifungal</p> <p>Uses ■ treats vaginal yeast infections</p> <p>Warnings ■ relieves external itching and irritation due to a vaginal yeast infection</p> <p>For vaginal use only.</p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor.</p> <p>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</p> <p>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). ■ if you do not get complete relief, ask a doctor before using another product ■ do not have vaginal intercourse ■ mild increase in vaginal burning, itching or irritation may occur</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>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 (1-800-222-1222) right away.</p> <p>Directions ■ before using this product, read the enclosed educational brochure for complete directions and information</p> <p>■ 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.</p> <p>■ children under 12 years of age: ask a doctor</p> <p>Other information ■ to open tube: unscrew cap, lift tab, and pull to remove foil seal prior to use ■ do not use if foil seal on tube opening is broken or missing ■ do not purchase if carton is open ■ store at room temperature 20° to 25°C (68° to 77°F) ■ before using any medication, read all label directions. Keep carton, it contains important information.</p> <p>Inactive ingredients benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polyethylene glycol, purified water, sodium phosphate monobasic, sorbitan monostearate</p> <p>Questions? Call 833-358-6431 Monday to Friday 8:00am to 7:00pm EST</p>
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Product of Italy
Rev. 06/2022

Code: GD/DRUGS/361 AAE34/03



SUNMARK Vaginal Cream with Reusable Applicator

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-793
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OCTYLDODECYL STEARATE (UNII: K6F16QGO28)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-793-76	1 in 1 CARTON	07/19/1993	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA074165	07/19/1993	

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 10/2022

Strategic Sourcing Services LLC