

CLOTRIMAZOLE- clotrimazole cream
Sun Pharmaceutical Industries, Inc.

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

PRINCIPAL DISPLAY PANEL - 45 g Carton

Cures Most Vaginal Yeast Infections

7 Day Treatment

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)

Vaginal Antifungal

Educational Brochure Enclosed

NDC 51672-2003-6

7 Day Treatment

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

Compare to the active ingredient in Gyne-Lotrimin® 7*



Cures Most Vaginal Yeast Infections

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

7 Day Treatment

LPK-1314-7
0915-7
M&T

NO VARNISH/NO AQ
NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT

Cures Most Vaginal Yeast Infections

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

7 Day Treatment

One 45 g (1.5 oz) Tube Of Clotrimazole Vaginal Cream USP (1%)
& 1 Reusable Applicator

Educational Brochure Enclosed

Cures Most Vaginal Yeast Infections

7 Day Vaginal Cream
Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

7 Day Treatment

T128B
8813
ENG1933



* This product is not manufactured or distributed by MSD Consumer Care Inc., a subsidiary of Merck & Co., Inc.



Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
Made in Canada

NO VARNISH
ON THIS FLAP

NO VARNISH
ON THIS FLAP

<p>Drug Facts (continued)</p> <p>Drug Facts (continued)</p> <p>• you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or a four-smelling vaginal discharge</p> <p>• if pregnant or breast-feeding, ask a health professional before use</p> <p>• keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>• 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</p> <p>• vaginal cream: insert one applicator of cream into the vagina at bedtime for 7 days in a row. Wash applicator after each use.</p> <p>• 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</p> <p>• do not use if carton is opened</p> <p>• to open, uncrew cap, use pointed end on cap to puncture seal</p> <p>• safely sealed: the tube opening should be sealed. If the seal has been punctured or is not visible, do not use the product.</p> <p>• store between 20° to 25° C (68° to 77° F)</p> <p>• see flap of carton or crimp of tube for lot number and expiration date</p> <p>Inactive ingredients</p> <p>benzyl alcohol, octylalcohol, oleyl esters wax, 2-oxy/decanol, polyorbate 60, purified water, sorbitan monostearate</p> <p>Questions or comments? call 1-866-923-4914</p>	
<p>Active ingredients</p> <p>Clotrimazole USP 1% (50 mg in each applicator), Vaginal antifungal</p> <p>Clotrimazole USP 1% (external cream)</p>	<p>Uses</p> <p>• treats vaginal yeast infections</p> <p>• relieves external itching and irritation due to a vaginal yeast infection</p>
<p>Warnings</p> <p>Do not use if you have never had a vaginal yeast infection diagnosed by a doctor</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>• vaginal itching and discomfort for the first time</p> <p>• lower abdominal, back, or shoulder pain, fever, chills, nausea,</p> <p>• vomiting, or four-smelling vaginal discharge.</p> <p>• you may have a more serious condition.</p> <p>• vaginal yeast infections often occur as once a month or 3 in 6 months.</p> <p>• you could be pregnant or have a serious underlying medical cause for other vaginal products. Condoms and diaphragms may be damaged and fail when exposed to the human immunodeficiency virus (HIV) that causes AIDS.</p>
<p>Purpose</p> <p>Vaginal antifungal</p>	<p>When using this product</p> <p>• 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).</p> <p>• do not have vaginal intercourse</p> <p>• mild increase in vaginal burning, itching or irritation may occur</p> <p>• if you do not get complete relief, ask a doctor before using another product</p> <p>• stop use and ask a doctor if</p> <p>• symptoms last more than 7 days</p> <p>• symptoms do not get better in 3 days</p>

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal
7 Day Treatment

7 Day Vaginal Cream

Cures Most Vaginal Yeast Infections

45 g Carton Label

NDC 51672-2003-6

7 Day Treatment

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

Compare to the active ingredient in Gyne-Lotrimin® 7*

ohm
LABORATORIES INC.

a SUN PHARMA company

Cures Most Vaginal Yeast Infections

7 Day Treatment

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

5261585
0625
70

Cures Most Vaginal Yeast Infections

7 Day Treatment

7 Day Vaginal Cream

Clotrimazole Vaginal Cream USP (1%)
Vaginal Antifungal

NO VARNISH/ NO AQ



One 45 g (1.59 oz) Tube Of
Clotrimazole Vaginal Cream USP (1%)
& 1 Reusable Applicator

Educational Brochure Enclosed

Cures Most Vaginal Yeast Infections
7 Day Vaginal Cream



*OHM and OHM Logo are trademarks of Ohm Laboratories, Inc. All other trademarks are the property of their respective owners.

Distributed by:
Ohm Laboratories Inc.
New Brunswick, NJ 08901
Made in Canada

T1288
B81.3
ENG1933

NO VARNISH
THIS FLAP

<p>Directions</p> <ul style="list-style-type: none"> • before using this product read the enclosed educational brochure for complete directions and information • adults and children 12 years of age and over: <ul style="list-style-type: none"> • 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. <p>Other information</p> <ul style="list-style-type: none"> • 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 trim of tube for lot number and expiration date <p>Inactive ingredients</p> <p>2-octyldodecanol, benzyl alcohol, cetostearyl alcohol, cetyl esters wax, polysorbate 60, purified water, sorbitan monostearate</p> <p>Questions or comments? call 1-866-923-4914</p>	<p>Warnings</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</p> <ul style="list-style-type: none"> • 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>When using this product</p> <ul style="list-style-type: none"> • 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • symptoms do not get better in 3 days • symptoms last more than 7 days
---	--

NO VARNISH

CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0K00R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2003-6	1 in 1 CARTON	12/04/1995	
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 - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2003)

Revised: 6/2025

Sun Pharmaceutical Industries, Inc.