

NDA 020574/S-006
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Gyne-Lotrimin³
Clotrimazole Vaginal Cream (2%)
 Vaginal Antifungal
Vaginal Cream

3 Disposable Applicators
 Cures most vaginal yeast infections

Drug Facts	Purpose
Active ingredients Clotrimazole 2% (100 mg in each applicator) Clotrimazole 2% (external cream)	Vaginal antifungal Vaginal antífungal
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 • if you do not get complete relief ask a doctor before using another product • 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 • you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or a foul-smelling vaginal discharge • symptoms last more than 7 days 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 applicator of cream into the vagina at bedtime for 3 days 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. Use 2 times daily for up to 7 days as needed. • children under 12 years of age: ask a doctor	

Drug Facts (continued)

Other information
 • store between 20° to 25°C (68° to 77°F)
 • see end panel of carton and tube crimp for lot number and expiration date
 • tamper-evident: do not use if seal embossed with "S" over tube opening is missing, open or broken

Inactive ingredients
 benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 80, purified water, sorbitan monostearate

Questions or comments?
 If you have questions or need more information on this product, call toll free 1-800-317-2185 between 8:00 AM and 5:00 PM Central Standard Time, Monday through Friday.

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