

NDA 20-574

Enclosure: Attachment A: Approved labeling text for the **carton** and **educational brochure**.

Attachment B: Approved labeling text for the **tube**.

Attachment C: Approved labeling text for the **carton** and **educational brochure**, to be used after 6 months following approval of this application or at the next printing of the product labeling, whichever comes first.

Attachment D: Approved labeling text for the **tube**, to be used after 6 months following approval of this application or at the next printing of the product labeling.

Attachment A:

Gyne-Lotrimin 3[®] Vaginal Cream

Carton

Hanging flap

Gyne-Lotrimin 3[®]
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

**3-Day
Treatment**

Front Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3[®]
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal

**3-Day
Treatment**

Educational Brochure Enclosed

One 21g (0.74 oz.) Tube of Vaginal Cream
(Clotrimazole (2%) (100 mg per applicator)
and 3 Disposable Applicators

Schering-Plough logo

Top Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3[®]
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

**3-Day
Treatment**

Bottom Panel

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

**3-Day
Treatment**

Side Panels

Cures Most Vaginal Yeast Infections

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

**3-Day
Treatment**

Back Panel

Gyne-Lotrimin 3 ®
Clotrimazole Vaginal Cream (2%)
Vaginal Antifungal
3 Disposable Applicators

**3-Day
Treatment**

Cures Most Vaginal Yeast Infections

GYNE-LOTRIMIN 3 ® Vaginal Cream is a 3-day treatment that cures most vaginal yeast infections. **If this is the first time you have had vaginal itching and discomfort, consult your doctor.** If you have had a doctor diagnose a vaginal yeast infection before and have the same symptoms now, use this cream as directed for 3 days in a row.

Active Ingredient: Clotrimazole (2%) (100 mg per applicator).

Use:

- For the treatment of vaginal yeast infections (*candidiasis*).

Warnings:

- **For vaginal use only. Do not use in eyes or take by mouth.**
- Do not use GYNE-LOTRIMIN 3 Vaginal Cream if you have any of the following signs and symptoms:

- fever (higher than 100°F).
- pain in the lower abdomen, back, or either shoulder.
- a foul-smelling vaginal discharge.
- While using GYNE-LOTRIMIN 3 Vaginal Cream, if you get a fever, abdominal pain, or a foul-smelling vaginal discharge, **stop using the product** and contact your doctor right away. You may have a more serious illness.
- If your symptoms do not improve in 3 days, or you still have symptoms after 7 days, you should call your doctor.
- If your symptoms return within 2 months, you should consult your doctor. You could be pregnant or there could be a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system (which may be due to HIV – the virus that causes AIDS).
- Contact your doctor if you get hives or a skin rash while using this product.
- Do not use tampons, douches, or spermicides while using this product.
- Do not rely on condoms or diaphragms to prevent sexually transmitted diseases or pregnancy. This product may damage condoms and diaphragms and cause them to fail.
- If pregnant or breast-feeding, ask a health professional before use.
- Do not use in girls less than 12 years of age.
- **Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Applicator and instructions are enclosed.

- Before using, read the enclosed brochure for complete instructions.
- To open: use cap to puncture seal.
- Insert one applicatorful of cream into the vagina at bedtime for 3 days in a row.

Inactive Ingredients: Benzyl alcohol, cetearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, purified water, sorbitan monostearate

Store at room temperature 15° - 30°C (59° - 86°F). Avoid heat over 30°C or 86°F.

See end flap of carton and end of tube for lot number and expiration date.

Important: Do not purchase if carton is opened. The tube opening should be sealed. If seal has been punctured or the embossed design **SP** is not visible, do not use the product. Return the product to the store where you bought it.

Medical questions should be answered by your doctor. If you have any other questions, or need more information on this product, call our TOLL-FREE Number, at 1-8XX-(XXX-XXXX), between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, Monday through Friday.

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