LABELLING STANDARD FOR INTRAVAGINAL ANTIFUNGAL AGENTS

CATEGORY: Imidazole antifungal agents

APPLICATION: Intravaginal cream, ointment, insert, ovule and suppository forms of imidazole antifungal agents for the treatment of vaginal yeast infection.

MEDICINAL INGREDIENTS and CONCENTRATION:

The finished product and all ingredients used in the manufacture of the product should comply with the specifications of Schedule B pharmacopoeial or equivalent standard.

The medicinal ingredients of a product complying with this monograph consist of the following ingredients when used singly within the limits given:

1. clotrimazole	1% cream or ointment 2% cream or ointment 10% cream or ointment 100 mg insert or ovule or suppository 200 mg insert or ovule or suppository 500 mg insert or ovule or suppository
2. miconazole	2% cream or ointment 100 mg insert or ovule or suppository 400 mg insert or ovule or suppository
3. tioconazole	6.5% cream or ointment 300 mg insert or ovule or suppository

NOTE: these ingredients are subject to the requirements of Part C, Division 8 of the Regulations to the Food and Drugs Act.

Acceptable combinations

Combinations of medicinal ingredients are not included in this labelling standard. The criteria for acceptability of packages containing two finished products, each with a single medicinal ingredient is dicussed in the dosage section.

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ADEQUATE DIRECTIONS FOR USE:
Indications:

For the treatment of vaginal yeast infection

Other acceptable claims:

-For the relief of vaginal itching, burning and discharge associated with vaginal yeast infection

-Cures most vaginal yeast infections

Dosage: **Table 1**

Ingredient	Concentration and Formulation	Duration of treatment
Clotrimazole	1% cream/ointment	once a day x 7 days
	2% cream/ointment	once a day x 3 days
	10% cream/ointment	single treatment
	100 mg insert/ovule/suppository	once a day x 6 days, or twice a day x 3 days
	200 mg insert/ovule/suppository	once a day x 3 days
	500 mg insert/ovule/suppository	single treatment
Miconazole	2% cream/ointment	once a day x 7 days
	100 mg insert/ovule/suppository	once a day x 7 days
	400 mg insert/ovule/suppository	once a day x 3 days
Tioconazole	6.5 % cream/ointment	single treatment
	300 mg insert/ovule/suppository	single treatment

Combination Packages

An additional tube of cream or ointment to be used concurrently with inserts, ovules or suppositories may be included in the package provided that:

(i) the cream/ointment is the same medicinal ingredient as the other dosage form in the package, and

(ii) the amount of cream provided is appropriate only for the treatment period of the other dosage form (ie. 1 to 7 days) not for a longer time period of use and,

(iii) the product labelling indicates that the additional cream is to treat external genital symptoms of vaginal yeast infection, such as itching and burning. Any indication that the external cream will cure the yeast infection is unacceptable.

Dosage Directions:

1. After reading the instructions enclosed,

   - apply 1 applicatorful of cream/ointment or,
   - insert a vaginal insert/ovule/suppository

   high in the vagina at bedtime.

(Note: detailed instructions for inserting and care of the applicator must accompany package).

2. Use even during menstruation

3. <u>For 3 to 7 day treatments</u> (see table 1, duration of treatment)

   -Repeat on **X** (3, 6 or 7) consecutive nights even if syptoms disappear.

4. To help prevent reinfection, wear cotton underwear.

Warnings:

1. Use only if you have already had a vaginal yeast infection diagnosed by a physician and you have the same symptoms now, otherwise consult your physician. These symptoms include itching and burning of the vagina and, sometimes, a white discharge.

2. If there is no improvement in 3 days or if symptoms have not disappeared within 7 days, then consult a physician as not all vaginal infections are caused by yeast.

3. Consult a physician if you have abdominal pain, fever or foul-smelling vaginal discharge before or during use of this medication.

4. If symptoms recur within 2 months consult a physician.

5. If you are pregnant, or think you may be pregnant or are nursing, do not use this product except on the advice of a physician.

6. Do not use in children under 12 years of age except on the advice of a physician.

7. If skin rash or new irritation occurs, discontinue use.

8. If you are at increased risk for sexually transmitted diseases, have multiple partners or change partners often, consult a doctor before starting each treatment.

NOTE: This labelling standard describes those requirements that are specific to this class of drugs. Other requirements described in the **Regulations to the Food and Drugs Act** and in the **Guide for the Labelling of Drugs for Human Use** should also be met.

Product Regulation Division
Bureau of Nonprescription Drugs

REFERENCES:

1. Department of Health and Human Services, Food and Drug Administration, Transcript of **Fetal and Maternal Drug Products Advisory Committee** meeting, "**Prescription to OTC Switch of Vaginal Formulations of Clotrimazole and Miconazole**", June 1990.

2. United States Pharmacopeial Convention,**Drug Information for the Health Professional**, Vol. 1B, United States Pharmacopeial Convention, Inc., 1989, pp1473-1477

3. American Hospital Formulary Service, **Drug Information,** American Society of Hospital Pharmacists, Inc., pp 2097-2106

4. Facts and Comparisons Division, **Drug Facts and Comparisons,** J.B. Lippincott Company, 1989, pp 1669-1671

5. American Medical Association, **Drug Evaluations Annual,** pp. 1358-1364, 1992.

Appendix I
Formulated Preparations

Proper Name	USP 1995	BP 1993	BPC 1976
Clotrimazole	X	X	
Clotrimazole Cream	X		
Clotrimazole Vaginal Tablets	X		
Miconazole	X		
Miconazole Nitrate	X	X	
Miconazole Nitrate Cream	X		
Miconazole Nitrate Vaginal Suppositories	X		