

This document is reference information about the products.  
Please confirm a document attached to a product definitely.

# OKINAZOLE®L600

Pharmacist Intervention  
Required Medicine

**Therapeutic agent for recurrent vaginal candidiasis; External drug for vagina**

Vaginal candidiasis is vaginitis caused by a fungus called Candida (a member of the mold family). Vaginal candidiasis causes itching of the vulva and changes in the appearance and amount of vaginal discharge, sometimes accompanied by heat sensation, pain, and swelling of the vulva. The discharge in vaginal candidiasis is like porridge (cottage cheese) or milky sake lees. This medicine improves symptoms of vaginal candidiasis.

**Use of this medicine is limited to patients who have been diagnosed with or treated for vaginal candidiasis by a doctor.**

**PRECAUTIONS**

**DON'Ts**

**(Failure to follow these precautions may worsen the clinical condition or cause adverse reactions.)**

**1. Do not take if**

- (1) you have not previously been diagnosed with or treated for vaginal candidiasis by a doctor.
- (2) you have recurrent episodes of vaginal candida (once within 2 months or at least twice over the previous 6 months) (repeated recurrence in a short period of time may indicate other diseases, such as diabetes mellitus).
- (3) you do not know whether the symptoms are caused by recurrence of vaginal candidiasis [Vaginal discharge is not porridge-like (cottage cheese-like) or milky sake-lees-like, or it produces an unpleasant odor. In such cases, the symptoms may be caused by diseases other than candidiasis.].
- (4) you have a fever or chills.
- (5) you have nausea or vomiting.
- (6) you have lower abdominal pain.
- (7) you have back pain or shoulder pain.
- (8) you have irregular or abnormal bleeding, or bloodstained vaginal discharge.
- (9) you have ulcers, blisters, or pain in the vagina or vulva.
- (10) you have pain during micturition or difficulty in micturition.
- (11) you have diagnosed with diabetes mellitus.
- (12) you are using anticoagulants, including warfarin.
- (13) you have experienced allergic reactions to this medicine or its ingredients.
- (14) you are pregnant or suspected of being pregnant.
- (15) you are a child under 15 years of age or an elderly person 60 years of age or older.

**2. Do not apply the following medicines to the vulva for 6 days after using this medicine.**

Dermatological preparations other than medicines for treatment of candidiasis



**CONSULTATION**

**1. Consult a doctor or pharmacist before use if**

- (1) you are under the care of a doctor.
- (2) you are breastfeeding.
- (3) you have experienced allergic reactions to medicines or other substances.

**2. Discontinue use immediately and consult a doctor or pharmacist showing this package insert if any the following symptoms occur after the medication, since it can be an adverse reaction.**

Affected area	Symptoms
Vagina	Pain (throbbing pain), sense of swelling (feeling swollen), redness, irritation, itching, heat sensation

**3. If symptoms do not improve after using this medicine for 3 days or do not resolve after using this medicine for 6 days, stop using this medicine and consult a doctor showing this package insert.**

**INDICATIONS**

Recurrence of vaginal candidiasis (**limited to persons who have been diagnosed with vaginal candidiasis or have received treatment for vaginal candidiasis by a doctor**)

**COMPOSITION  
(per tablet)**

Oxiconazole nitrate ..... 600 mg  
(Additives: crystalline cellulose, hydroxypropylcellulose, citric acid hydrate, and magnesium stearate)

## DOSAGE AND ADMINISTRATION

For adults ( $\geq 15$  years and  $< 60$  years of age), insert one tablet deep into the vagina once (preferably before bedtime). **If symptoms do not improve after using this medicine for 3 days or do not disappear after using this medicine for 6 days, consult a doctor.**

Age	Dosage
Adult ( $\geq 15$ years and $< 60$ years of age)	One tablet (preferably before bedtime)
$< 15$ years or $\geq 60$ years of age	Do not use.

### <Precautions regarding dosage and administration>

- (1) Follow the designated dosage and administration.
  - (2) **This medicine is designed to be effective enough for a single use. Do not use additional vaginal tablets or suppositories for Candida, because the medicine used will remain in the vaginal tract after one use and work gradually.**
  - (3) This medicine should be used only in the vagina and must not be taken by mouth. If you accidentally take this medicine, consult a doctor immediately.
  - (4) Do not use this medicine during menstruation. If you get a period within 6 days of use, consult a doctor because healing etc., must be confirmed. (Sufficient effectiveness of medication may not be achieved during menstruation.)
  - (5) If, within 6 days of use, a vaginal tablet does not dissolve and comes out in the same shape and size as inserted, do not insert additional vaginal tablets at your own discretion and consult your doctor or pharmacist.
- \*This medicine remains and exerts its effect in the vagina, and then it is gradually excreted from the body; white lumps and paste-like substances may come out.

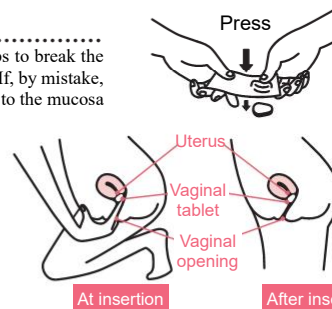
### How to use the vaginal tablet

#### How to take out a tablet

Wash your hands and fingers with soap and water, then press the blister with fingertips to break the aluminum foil on the reverse side and tip the vaginal tablet out, as shown on the right. (If, by mistake, you use the product without taking the tablet from the sheet, accidents such as damage to the mucosa may occur.)

#### Insertion method

Squat with legs spread apart and insert a vaginal tablet into the deepest part of the vagina with your fingertips, as shown on the right. (Do not use applicators, etc.) After inserting the tablet, thoroughly wash hands and fingers that come into contact with the affected area with soap. There is no specific direction to insert a vaginal tablet; however, it is recommended to insert it from the thin side as it is easy to insert.



**This concludes the treatment for recurrent vaginal candidiasis.**

However, lifestyle precautions should be followed because Candida may remain in the vaginal tract for 6 days after use.

After 3 days: Consult your doctor if symptoms do not improve.

After 6 days: Consult your doctor if symptoms do not disappear.

### PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Store in a cool, dry place, away from direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer or store in another container.  
(May lead to misuse or quality deterioration.)
- (4) Do not use after the expiration date.



### PRECAUTIONS IN DAILY LIFE

- (1) **If vaginal candidiasis recurs, your partner may be infected. Inform him that you are infected with vaginal candidiasis, and if he has uncomfortable symptoms, such as itching and redness of his genital organ, consult a doctor immediately.**
  - (2) Avoid sexual intercourse for 6 days after the use of this medicine to prevent transmission to the partner.
  - (3) Do not use spermicides for 6 days after the use of this medicine to prevent irritation in the affected area.
  - (4) Avoid washing inside the vagina by yourself to maintain the effectiveness of medicine.
  - (5) Gently wash the vulva with warm water only without using soap to avoid soap irritation during bathing.
  - (6) Since Candida tends to grow in high temperature and humidity, it is important to keep it dry as much as possible.
- Pay attention to the following points.
- Dry the outside of the vagina thoroughly after taking a bath or swimming. Change wet swimming suits as soon as possible.
  - When sanitary products, such as pantliners, are used, change them frequently.
  - Wear breathable underwear, such as cotton.
- (7) Use clean underwear and towels daily and do not share towels and other items with other family members to avoid infection.
  - (8) Candida normally lives in the digestive tract. Wipe from front to back to avoid infection from the intestine after using the toilet.
  - (9) Do not scratch the vulva even if itching occurs. Scratching can cause severe irritation and spread of infection.



Marketing Authorization Holder  
TANABE PHARMA CORPORATION  
3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan