

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

OKINAZOLE®L100 Class-1 pharmaceutical product

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 been diagnosed with vaginal candidiasis or if you have not received treatment for vaginal candidiasis by a doctor
- (2) you have repeatedly suffered from vaginal candidiasis at an interval of less than 2 months or if you have been infected with candida at least twice over the previous 6 months even if more than 2 months have intervened between episodes
- (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 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
- (12) you have treated with anticoagulants including warfarin
- (13) you have suffered from allergic symptoms due to this medicine or its ingredients
- (14) you are pregnant or suspected of being pregnant
- (15) you are younger than 15 years (age <15 years) or elderly persons 60 years or older

2. Do not apply the following medicines to the vulva while using this medicine

Dermatological preparations other than medicines for treatment of candidiasis



CONSULTATION

1. Consult a doctor, pharmacist before use if

- (1) you are under the care of a doctor
- (2) you are breastfeeding
- (3) you have ever had an allergic reaction to a medical product

2. If any of the following symptoms occur after medication, they may be adverse reactions, so discontinue use immediately, and consult a doctor or pharmacist showing this Package Insert:

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

3. If symptoms do not improve after using this product for 3 days or do not resolve after using this product for 6 days, stop using this product 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)

DOSE AND ADMINISTRATION

An adult (15 years ≤ age < 60 years) inserts 1 tablet deep into the vagina once daily (preferably before sleep). Use this medicine for 6 consecutive days. If symptoms do not improve after using this product for 3 days or do not resolve after using this product for 6 days, consult a doctor.

Age	Dosage	Frequency
Adult (15 years ≤ age < 60 years)	1 tablet	Once a day
<15 years or ≥ 60 years	Not recommended	

<Precautions regarding dosage and directions>

- (1) Please follow the designated dosage and directions.
- (2) This product should be used only in the vagina and must not be taken by mouth. If you accidentally take the product, consult a doctor immediately.
- (3) Continue to use for 6 days from the start of use even if symptoms disappear earlier.
- (4) Do not use this product during menstruation. If you get a period during use, stop using the product. In such a case, since confirmation of healing, etc. are required, consult a doctor (sufficient effectiveness of medication may not be achieved during menstruation).

COMPOSITION

Per daily dose (1 tablet)

Oxiconazole nitrate 100 mg
Additives: lactose hydrate, crystalline cellulose, hydroxypropylcellulose, citric acid hydrate and magnesium stearate

PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Store in a cool and 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.



Manufactured and distributed by
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Effective against intolerable itching and unpleasant discharge

OKINAZOLE®L100

OKINAZOLE L100 is a medicine for the recurrence of vaginal candidiasis, containing the antifungal ingredient oxyconazole nitrate as an active ingredient.

Characteristics of OKINAZOLE®L100

Sterilizes Candida

Oxyconazole nitrate, an antifungal ingredient developed in Our Company, disrupts cell membranes of Candida and exhibits excellent bactericidal activity.

Improves also symptoms of the vulva

It improves not only the symptoms of the vagina such as abnormal discharge but also symptoms of the vulva (itching, redness, and swelling).

Effective against treatment-resistant bacteria

It is also effective against Candida glabrata, a bacterium that is often resistant to treatment.

Vaginal tablet that is hard to come off

As it dissolves and spreads quickly by absorbing water in the vagina, it is less likely to come out from the vagina.

* This medicine remains and exerts its effect in the vagina, and then it is gradually excreted from the body, so white lumps and paste-like substances may come out.

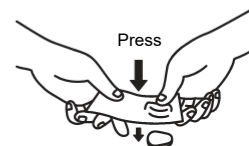
PRECAUTIONS IN DAILY LIFE

- (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 during the use of this product to prevent transmission to the partner.
- (3) Do not use spermicides during the use of this product in order to prevent irritation in the affected area.
- (4) Avoid washing inside the vagina by yourself to maintain the effect of medicine.
- (5) Gently wash the vulva with warm water only without using soap in order 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. Please pay attention to the following points.
 - Dry the outside of the vagina thoroughly after taking bath or swimming.
 - Change wet swimming suits as soon as possible.
 - When sanitary products such as pantliners are used, change frequently.
 - Wear breathable underwear such as cotton.
- (7) Use clean underwear and towels daily and do not share towels, etc. 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.

How to use the vaginal tablet:

How to take out a tablet:

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

Wash your hands and fingers thoroughly with soap, 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 an applicator 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, but it is recommended to insert it from the thin side as it is easy to insert.

