

◆Meditreat cream is a drug to treat symptoms in the vulva with miconazole nitrate as main ingredient. ◼Miconazole nitrate relieves symptoms of vaginal candidiasis by killing Candida, the causative agent of vaginal candidiasis. ◼Meditreat cream relieves itching in the vulva associated with rash caused by recurrent vaginal candidiasis.

Indication

Vulva itching with rash due to recurrent vaginal candidiasis (limited to persons who have previous diagnosis/treatment by a physician)

If you have vaginal symptoms (vaginal discharge, feeling hot, etc.), use a vaginal suppository (a drug to be inserted in the vagina) concurrently.

The drug relieves the pudendal symptoms caused by Candida but is not for intravaginal treatment.

Pudendal symptoms such as itching, rash, and feeling hot are caused by Candida spp. in the vagina, which also affects the vulva.

Use this drug when you have itching on pudendal skin associated with rash, such as redness and sores.

Dosage and administration

For an adult (aged ≥ 15 years old and < 60 years old), apply the proper dose on the affected site 2 to 3 times a day. If symptoms are not relieved after using the drug for 3 days or if symptoms are not resolved after using the drug for 6 days, seek treatment from a physician.

Pudendal symptoms only: Use this drug. Combination use with vaginal suppository (drug to be inserted in vagina) is desirable.

Concurrent vaginal symptoms (vaginal discharge, feeling hot, etc.): Use this drug concurrently with vaginal suppository (drug to be inserted in vagina).

Comply with the prescribed dosage and administration instructions.

Apply only around the vagina (vulva).

Attention should be paid so that the medicine will not come into contact with eyes. In case the medicine comes into contact with eyes, immediately rinse them with water or lukewarm water, and immediately seek an ophthalmologist for medical treatment.

Wash your hands well before and after use.

Do not use the drug during your period. If your period starts during the use, stop using the drug. In such a case, seek treatment from a physician to confirm whether the symptoms have resolved. (During a period, the drug may leak, and sufficient effects may not be achieved.)

Take a bath or wash your vaginal area with warm water before use.

ingredient and amount

In 1 g
Miconazole nitrate 10mg

Excipients

Polyoxyethylene cetyl ether, Self-emulsifying Glyceryl monostearate, Butyl parahydroxybenzoate, Isopropyl myristate, Liquid paraffin, Cetanol

Precautions

When not to use the product

(If you do not follow these instructions, the current symptoms may worsen or adverse reactions are more likely to occur.)

This product should not be used in the following persons:

Persons with seemingly first onset (Other diseases may be the cause in persons with first onset and may require diagnosis by a physician.)

Persons who have had an allergic symptom to the drug or the drug ingredients. (Allergic symptoms may recur in the use of this drug.)

Children under 15 years old or persons ≥ 60 years old. (The symptom in children under 15 years old is highly likely the first onset. The symptom in persons ≥ 60 years old may be a mixed infection caused by other disease or other bacteria.)

Pregnant women or women suspected of being pregnant. (Take thorough precaution in using the drugs, and consult with a specialist doctor for instructions.)

Persons with fever, chill, lower abdominal pain, shoulder and back pain, colored or bloody vaginal discharge, fishy vaginal discharge, menstruation stopped, irregular or abnormal vaginal bleeding, ulcer, edema, or sores in the vagina or vulva (This may possibly be other diseases that require diagnosis by a physician.)

Persons diagnosed as having the following:

Diabetes (The disease may be frequently repeated, thus requiring diagnosis by a physician.)

Persons on anticoagulants, such as warfarin. (Bleeding tendency, which is an action of warfarin, may be enhanced.)

Persons repeating this disease frequently (once in 1 or 2 months or at least twice in 6 months).

Recurrent vaginal candidiasis is suspected. (If it is difficult to assess by yourself, seek diagnosis from a physician.)

Do not use in the following sites.

Sites other than the vagina (pudendum) and its surrounding area. (The drug should not be used in sites other than the vulva.)

Consultation

The following persons should contact a physician or pharmacist for a consultation before using the drug:

Patients undergoing medical treatment from a physician

(The drug may affect the action of other drugs prescribed by a physician.)

Persons who have had an allergic symptom to drugs.

(Persons who had allergic reaction to a drug may be allergic to the drug.)

Nursing women (Thorough precaution is required for the use of the drug.)

The following symptoms may occur after using the drug. If these symptoms persist or worsen, discontinue the use of this drug, and show this document to a physician or pharmacist for a consultation.

Skin around the vagina (pudendum): itching, rash/redness, eruption, feeling hot, erosion, irritation, phlyctenule, swelling, dryness/fissure, and exfoliation

(They are considered allergic symptoms to the drug or powerful pharmacological actions of the drug. In such cases, the continuous use of the drug may worsen the symptoms.)

If the symptoms do not improve after using the drug for 3 days or if the symptoms do not resolve after using the drug for 6 days, seek medical treatment from a physician. (The symptoms may be severe or caused by other diseases.)

If you use the cream alone, do not judge the symptoms by yourself, but seek medical treatment from a physician.

(Symptoms may be severe or caused by other diseases.)

Precautions for storage and handling

Avoid direct sunlight, and store the product in a cool place with an air tight closure on.

Store the product beyond the reach of children.

Do not transfer the drug to other containers. (It may lead to misuse or quality deterioration.)

Do not touch the product with contraceptive latex products, such as condoms and pessaries. (The contraceptive products may be deteriorated or damaged.)

Do not use the product past the expiration date. Even within the expiration date, try to use it up as soon as possible once it is opened (to assure the quality).

41

【Disclaimer on Multilingual OTC Product Information】

•This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.

•Multilingual product information is a translation of the product labeling written in Japanese and provided for your information only. It does not warrant that its contents and the product itself conforms to laws and regulations in countries other than Japan.

•Multilingual product information is a tentative translation by the provider (or Our Company), and may be modified or altered without notice.

•The provider (or Our Company) assumes no responsibility for any occurred problem attributable to the contents of the multilingual product information.