

Gino-Mia V

Clotrimazol Vaginal Compresses 100 mg

Composition:

Each compressed vaginal contains:
Clotrimazole USP 100 mg
Excipients QS

therapeutic indications

Vaginal compresses Gino-Mia V 100mg are recommended for the treatment of Candida vaginitis.

Posology and method of administration

The tablets should be inserted into the vagina, or as high as possible, using the supplied injector. This is best achieved when lying down with the legs folded upwards.

Adults:

Two tablets should be inserted daily (preferably at night) during three consecutive days. Alternatively, a pessary can be inserted daily for six days, preferably at night. A second treatment can be performed if necessary.

There is no separate psychological scheme for the elderly.

Gino-Mia V Vaginal tablets require moisture in the vagina in order to dissolve completely, otherwise pieces of the tablet not dissolved can disintegrate outside the vagina. Compressed tablets that have not dissolved may be noted by women who present with vaginal secra. To help prevent this, it is important that the tablet is inserted as high as possible into the vagina.

Generally:

- o Treatment should not be carried out during the menstrual period due to the risk of compression by washing with menstrual flow. The treatment should be completed before the onset of menstruation.

Do not use tampons, intravaginal douches, spermicides or other vaginal products to use this product.

A sexual vaginal relationship should be avoided in case of vaginal infection and during the use of this product, because the partner may be infected.

Children:

Should not be used in children under 16 years of age.

Contra-indications

Hypersensitivity to Clotrimazole or any other ingredient of this medicine.

Advertisements and special precautions for use

Medical advice should be sought if the first time a patient presents with symptoms of vaginitis caused by Candida.

Before using Gino-Mia V 100mg tablets, medical advice should be obtained, if any of the following two are applicable:

- More than two infections of vaginitis by candida in the last six months.
- Previous history of sexually transmitted disease or exposure to a partner with a sexually transmitted disease.
- Pregnancy or suspicion of pregnancy.
- Under 16 years of age or over 60 years of age.
- Hypersensitivity known to imidazole or other vaginal antifungal products.

Gino-Mia V 100mg Vaginal tablets should not be used if the patient has any of the following symptoms and medical advice should be sought:

- Irregular vaginal bleeding.
- Abnormal vaginal bleeding or a cloudy discharge of blood.
- Vulvar or vaginal ulcers, boils or wounds.
- lower abdominal pain or dysuria.
- Any adverse events such as redness, irritation or swelling associated with the treatment.
- fever or chills.
- Nausea or vomiting.
- Diarrhoea.

- Vaginal discharge with fetid odor.

Patients should be advised to consult their doctor if symptoms are not relieved within a week of using Gino-Mia V 100mg tablets. These tablets can be used again if a Candida infection returns after 7 days. However, if a candidal infection recurs more than twice in six months, patients should be advised to consult a doctor.

Interaction with other medications and other forms of interaction

Laboratory tests suggest that, when used in combination, these products may cause damage to contraceptive pills. Consequently, the effectiveness of such contraceptives may be reduced. These patients should be advised to use alternative precautions for at least five days after use of this product.

A concomitant medication with clotrimazole vaginal and tacrolimus oral (FK-506; immunosuppressor) may lead to an increase in plasma levels of tacrolimus and similarly with sirolimus. These patients should, therefore, be closely monitored for signs and symptoms of overdose of tacrolimus or sirolimus, as necessary to determine the respective

plasma levels.

Fertility, pregnancy and lactation

Fertility:

No studies have been conducted in humans on the effects of clotrimazole on fertility; However, these studies in animals did not demonstrate any effects of the drug on fertility.

Gravidity:

Data regarding the use of clotrimazole in pregnant women are limited. Animal studies with clotrimazole show reproductive toxicity at higher or higher doses (see section 5.3). Given the low systemic exposures to clotrimazole after vaginal treatment, no harmful effects are predicted in relation to reproductive toxicity.

O clotrimazole can be used during pregnancy, but only under the supervision of a doctor or partner.

During pregnancy, the tablet should be inserted without using the Applicator.

Lactation:

The pharmacodynamic/toxicological data available in animals show excretion of clotrimazole/metabolites in milk after intravenous administration (see section 5.3). A risk to the infant cannot be excluded. A decision should be made whether to discontinue or discontinue therapy with clotrimazole, taking into account the benefit of therapy for the child and the benefit of therapy for the woman.

Effects on the ability to direct and use machines

The medicine does not affect or have appreciable effect on the ability to drive or use machines.

undesirable effects

As the desirable effects listed are based on spontaneous notifications, it is not possible to assign an exact frequency of occurrence to each one.

Functions of the immunological system:

Allergic reactions (syncope, hypotension, dyspnea, urticaria, prurido).

Reproductive system and breast disorders:

Genital desquamation, prurido, cutaneous eruption, edema, erythema, discomfort, pain, irritation, pelvic pain, vaginal bleeding.

Gastrointestinal problems:

do abdominal.

overdose

No risk of acute intoxication is observed, as it is unlikely to occur after a single vaginal or dermal application of an overdose (application to a large area under conditions favorable to absorption) or oral ingestion without advertising. There is no specific antidote.

However, in any case of accidental oral ingestion, routine measures, such as gastric lavage, should be performed only if clinical symptoms of overdose appear to return (for example, dizziness, nausea or vomiting). A gastric lavage should be performed only as the airways can be adequately protected.



Special Instructions for Use or Applicator:

1. Before application, cover the aluminum Enter a pessary.
2. Carefully insert the nozzle containing the pessary. As deeply as possible in the vagina. (This is done better given the cost)
3. Empurre or pessario for a vagina. Removing the Applicator
4. After use, remove the piston completely, pulling out for the applicant B. After this, make both Just pour (not boil) water with soap and dry completely.

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