

Clotrimaderm

Clotrimazole vaginal cream USP, 1% and 2%

Presentation

CLOTRIMADERM Vaginal Cream USP 1%:

Tubes each containing 45g cream, 10mg clotrimazole per gram (1%) pack with one reusable applicator and patient instruction sheet.

CLOTRIMADERM Vaginal Cream 2%:

Tubes each containing 25g cream, 20mg clotrimazole per gram (20%) pack with one reusable applicator and patient instruction sheet.

Uses

Actions

The primary mode of action of clotrimazole appears to be on the cell membrane of the fungi, damaging the permeability barrier.

Pharmacokinetics

Clotrimazole cream (CLOTRIMADERM) containing C₁₄-labelled clotrimazole administered intravaginally to five women (four without gynaecological disorders and one with Candida vaginitis). A maximum serum level of 0.01mg/ml was found between 10 and 30 hours after administration.

Six hours after application of labelled topical clotrimazole the concentrations ranged from 100mg/cm³ in the subcutis. No measurable radioactivity was found in the serum within 48 hours after application of 0.8g of the cream.

Indications

CLOTRIMADERM vaginal cream is indicated for the topical treatment of vulvovaginal candidiasis.

Dosage and Administration

CLOTRIMADERM (Clotrimazole) VAGINAL CREAM USP 1%

Once daily, preferably in the evening for six successive days, the applicator should be filled with cream (approx 5g) and inserted as deeply as possible into the vagina with the patient lying on her back.

For relief of external vulvar itching a small amount of cream should be squeezed onto the finger and applied gently to the irritated area of the vulva once to twice daily.

The 45g tube provides for sufficient cream for both intravaginal and local treatment.

CLOTRIMADERM (Clotrimazole) VAGINAL CREAM 2%

Once daily, preferably in the evening for three successive days, the applicator should be filled with cream (approx 5g) and inserted as deeply as possible into the vagina with the patient lying on her back.

For relief of external vulvar itching a small amount of cream should be squeezed onto the finger and applied gently to the irritated area of the vulva once to twice daily.

The 25g tube provides for sufficient cream for both intravaginal and local treatment.

Clotrimazole Cream USP 1% may also be used for application to the glans penis of the partner which may help prevent reinfection of the female.

Contraindications

Known hypersensitivity to clotrimazole.

Warnings and Precautions

If evidence of local intolerance develops, consider withdrawal of the drug and institution of appropriate therapy.

Use during Pregnancy

CLOTRIMADERM (Clotrimazole 1%, 2%) Vaginal Cream: Although intravaginal application of clotrimazole has shown negligible absorption from normal and inflamed human vaginal mucosa, CLOTRIMADERM Vaginal Cream 1% and 2% should not be used during pregnancy except on the advice and under the supervision of a physician.

Use during Lactation

It is not known whether this drug is excreted in human milk, therefore caution should be exercised when CLOTRIMADERM Vaginal Cream is used by a nursing mother.

Adverse Effects

CLOTRIMADERM Vaginal Cream is generally well tolerated after local application. The following have been reported infrequently: erythema, stinging, blistering, peeling, oedema, pruritis, urticaria and general irritation.

Interactions

Not reported for CLOTRIMADERM Vaginal Cream.

Overdosage

None reported.

Pharmaceutical Precautions

Store below 30 degrees celsius.

Medicines Classification

CLOTRIMADERM (Clotrimazole 1%) Vaginal Cream and CLOTRIMADERM (Clotrimazole 2%) Vaginal Cream: Pharmacist Only Medicine.

Package Quantities

CLOTRIMADERM Vaginal Cream (1% Clotrimazole) 45g
CLOTRIMADREM Vaginal Cream (2% Clotrimazole) 25g

Further Information

Nil

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