SCHEDULING STATUS: S1

PROPRIETARY NAME AND DOSAGE FORM

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

COMPOSITION

Active ingredient:

Each 1 g of cream contains:

Clotrimazole 10 mg

Preservative: Nipastat 0,275 % (m/m)

The other ingredients are: Cetostearyl alcohol, cremophor A6, cremophor A25, imidurea, liquid paraffin, propylene glycol, purified water.

PHARMACOLOGICAL CLASSIFICATION

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION

Pharmacodynamic Properties

Clotrimazole is a broad spectrum imidazole antimycotic with fungicidal properties. It inhibits the biosynthesis of ergosterol for the cytoplasmic membrane and leads to the accumulation of 14-α-methyl sterols. These methyl sterols may disrupt the close packing of acyl chains of phospholipids, impairing the functions of certain membrane-bound enzymes, thus altering the permeability of the cell wall membrane with the loss of essential intracellular elements and inhibiting the growth of the fungi.

Pharmacokinetic Properties

Approximately 3 – 10 % of clotrimazole is absorbed systemically from the vagina. It is rapidly metabolised in the liver to inactive compounds and excreted in bile. Fungicidal concentrations can remain in the vagina for as long as 3 days after vaginal application.

INDICATIONS

Vaginitis or vulvo-vaginitis due to fungi, mainly *Candida* species. For the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (vaginal candidiasis).

CONTRAINDICATIONS

Hypersensitivity to clotrimazole or to other azole antifungals.

Hypersensitivity to any of the excipients in CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

WARNINGS AND SPECIAL PRECAUTIONS

- The safety of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM in the first trimester of pregnancy and lactation has not been established (see PREGNANCY AND LACTATION).
- If skin rash or new irritation occurs, the use of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM should be discontinued (see CONTAINDICATIONS).
- Direct contact with CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM may reduce the effectiveness and safety of latex products such as condoms and diaphragms. Patients should avoid concurrent use of latex barrier devices during treatment and for 3 days after discontinuing treatment.
- Recurrent yeast infections may be caused by organisms other than yeasts or may be a sign of other conditions, such as diabetes or impaired immune function. A patient must be referred to a medical practitioner in this regard.
- Unmedicated tampons may absorb vaginal creams, and are not recommended for use concurrently with CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

Effects on Ability to Drive and Use Machines

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM is not expected to affect the ability to drive or use machinery.

Porphyria

Dermatological clotrimazole may be used as a drug of first choice and no precautions are needed

INTERACTIONS

Approximately 3-10 % of clotrimazole is absorbed systemically after vaginal application and may interact with hepatic CYPs as substrates and inhibitors. Interactions are possible with medicines metabolised by the cytochrome P450 system and some drugs may exhibit elevated plasma concentrations when co-administered with clotrimazole (see Pharmacokinetic Properties).

PREGNANCY AND LACTATION

Pregnancy

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM should not be used in the first trimester of pregnancy as the safety in this regard has not been established.

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM may be used during the second and third trimesters of pregnancy on the advice of a medical practitioner.

Women of Childbearing Potential

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM may damage latex contraceptives like condoms and diaphragms. Patients should avoid concurrent use of latex barrier devices and use additional contraceptive measures during local application treatment and for 3 days after discontinuing treatment (see WARNINGS AND SPECIAL PRECAUTIONS)

Lactation

The safety of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM in lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Please refer to the Patient Information Leaflet for illustrated instructions.

Fill enclosed vaginal applicator to the top (i.e. 5 g CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM). Insert deeply into the vagina every night on retiring for six consecutive days. This is

best achieved when lying on the back with the legs pulled in a little towards the body.

If individual cases should require it, two applications of 5 g vaginal cream can be used daily, i.e. one in the morning and one in the evening, for 6 to 12 days.

The treatment should not be carried out during menstruation but should be completed before menstruation begins.

For candida vulvitis or vulvo-vaginitis, the vaginal cream should be applied thinly to the external genitalia 2 or 3 times a day for 1 to 2 weeks. For the prevention of re-infection, the partner should be treated locally with CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM at the same time.

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM does not normally stain underwear.

SIDE EFFECTS

Immune system disorders

Less frequent: Contact allergic dermatitis, hypersensitivity reactions including skin rash or hives

Gastrointestinal disorders

Less frequent: Lower abdominal cramps or pain

Renal and urinary disorders

Frequency unknown: Increase in urinary frequency

General disorders and administrative site conditions

Less frequent: Vaginal burning, itching, irritation, discharge or other irritation not present before therapy. Burning or irritation of penis of sexual partner. Headache.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See **SIDE EFFECTS.**

In case of accidental ingestion, gastrointestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

IDENTIFICATION

Soft white cream.

PRESENTATION

50 g aluminium tube with white plastic screw cap plus 6 vaginal applicators.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

27/20.2.2/0125

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Phyto OTC Health (Pty) Ltd.

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