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ADMINISTRATIVE INFORMATION FOR CANDIFEM VAGINAL CREAM

1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS

1. NAME OF MEDICINAL PRODUCT
Candifem Vaginal Cream

2. QUALITATIVE QUANTITATIVE FORMULA

Sr.no.	Drug name	Scale % w/w	Standard quantity per kg
1.	Miconazole USP	2 %	20.000 g
2.	Ornidazole	2 %	21.000 g
3.	Propylene Glycol BP	9 %	90.000 g
4.	Macrogol Cetostearyl Ether BP (Cetomacrogol 1000)	3 %	30.000 g
5.	Cetostearyl Alcohol BP	7 %	70.000 g
6.	White Soft Paraffin BP	7 %	70.000 g
7.	Propylparaben BP	0.01%	0.100 g
8.	Methylparaben BP	0.1 %	1.000 g
9.	Citric Acid Monohydrate BP	q.s.	Approx. 0.100 g
10.	Purified Water BP	q.s	Approx. 735.000 g

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3. PHARMACEUTICAL FORM
Cream

4. CLINIUCAL PARTICULARS
4.1 Therapeutic indications
Candifem Vaginal Cream is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:
- Bacterial Infections
- Fungal And Bacterial Infections
- Vulvovaginal Candidiasis
- Vaginal Yeast Infections
- Napkin Rash
- Paronychia
- Protozoan Infections
- Infections During Surgical Procedures

4.2 Posology and method of administration

Adult: Mouth/Throat
Oropharyngeal candidiasis as 20 mg/g (24 mg/mL) gel: 2.5 mL 4 times/day.
Intestinal candidiasis As 20 mg/g (24 mg/mL) gel: 20 mg/kg/day, in 4 divided doses. Max: 250 mg (10 mL) 4 times/day.
Vulvovaginal candidiasis as 2% cream: Apply intravaginally at bedtime as a single dose for 10-14 days or bid for 7 days. As pessary: 100 mg/day for 7 or 14 days, 100 mg bid for 7 days, 200 mg or 400 mg/day for 3 days or 1,200 mg as single dose.
Topical Skin fungal infections as 2% cream, lotion or powd: Apply thinly over affected area bid for 2-6 wk.
Nail fungal infections as 2% cream: Apply over affected area 1-2 times/day

4.3 Contraindications
Hypersensitivity to Candifem Vaginal Cream is a contraindication. In addition, Candifem Vaginal Cream should not be taken if you have the following conditions:
- Epilepsy
- Hepatic impairment
- Hypersensitivity
- Lactation
- Multiple sclerosis
- Porphyria
- Pregnancy
- Renal or hepatic impairment

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4.4 Special warnings and precautions for use

Before using this drug, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Abdominal pain, chills, fever and nausea
- Avoid contact with eyes and oral cavity
- Consult your doctor before taking this medicine if having epilepsy and multiple sclerosis
- Do not drive a vehicle or operate heavy machinery after consuming the medicine
- Do not take the medicine on empty stomach
- Foul-smelling vaginal discharge

4.5 Pregnancy and lactation

Not Available

4.6 Effects on ability to drive and use machines

None.

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4.7 Overdose

- Do not take more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Candifem Vaginal Cream, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.
- Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.
- Please consult your physician or pharmacist or product package for more information

5. Pharmacological properties

5.1 Pharmacodynamic properties

Miconazole is an anti-fungal medication related to fluconazole (Diflucan), ketoconazole (Nizoral), itraconazole (Sporanox), and clotrimazole (Lotrimin, Mycelex). It is used either on the skin or in the vagina for fungal infections. Miconazole was approved by the FDA in 1974. Miconazole prevents fungal organisms from producing vital substances required for growth and function. This medication is effective only for infections caused by fungal organisms. It will not work for bacterial or viral infections

Miconazole interacts with 14-α demethylase, a cytochrome P-450 enzyme necessary to convert lanosterol to ergosterol. As ergosterol is an essential component of the fungal cell membrane, inhibition of its synthesis results in increased cellular permeability causing leakage of cellular contents. Miconazole may also inhibit endogenous respiration, interact with membrane phospholipids, inhibit the transformation of yeasts to mycelial forms, inhibit purine uptake, and impair triglyceride and/or phospholipid biosynthesis.

Ornidazole is a 5-nitroimidazole derivative active against protozoa and anaerobic bacteria. It is converted to reduction products that interact with DNA to cause destruction of helical DNA structure and strand leading to a protein synthesis inhibition and cell death in susceptible organisms.

After passive absorption into bacterium cell, the nitro group of ornidazole is reduced to amine group by ferrodoxin type redox system. The formation of redox intermediate intracellular metabolites is believed to be the key component of microorganism killing for Ornidazole. The drug is active against anaerobic bacteria viz. Peptostreptococcus, Clostridium, B. fragilis, Prevotella, Porphyronomas, Fusobacterium and protozoa viz. E. histolytica, T. vaginalis, G. intestinalis etc.

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5.2 Pharmacokinetic properties (Miconazole)

Miconazole inhibits ergosterol biosynthesis thus damaging fungal cell wall membrane and increases its permeability, allowing leakage of nutrients.

Absorption: There is little absorption through skin or mucous membranes when miconazole nitrate is applied topically.

Distribution: Absorbed miconazole is bound to plasma proteins (88.2%) and red blood cells (10.6%).

Metabolism and Excretion: The small amount of miconazole that is absorbed is eliminated predominantly in faeces as both unchanged drug and metabolites.

Pharmacokinetic (Ornidazole)

Absorption: Readily absorbed (oral and intravaginal); peak plasma concentrations after 2 hr (oral), 12 hr (intravaginal).

Distribution: Body tissues and fluids (wide), CSF. Protein-binding: <15%.

Metabolism: Hepatic.

Excretion: Via urine (as conjugates and metabolites), via faeces (small amounts); 12-14 hr (elimination half-life).

5.3 Preclinical safety Data

Product containing simple, widely used, well documented ingredients which are subjects of current pharmacopeias so the above data is not required.

6. Pharmaceutical particulars

6.1 List of excipients

Miconazole IP/USP

Ornidazole I (contains 5% Process Excess)

Propylene Glycol IP/BP

Macrogol Cetostearyl Ether BP (Cetomacrogol 1000)

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Cetostearyl Alcohol IP/BP

White Soft Paraffin IP/BP

Propylparaben IP/BP

Methylparaben IP/BP

Citric Acid Monohydrate IP/BP

Purified Water IP/BP

(@ 5% Excess)

6.2 Incompatibilities
None

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store below 30 ^{0}C.