

**MODULE -1**  
**ADMINISTRATIVE INFORMATION FOR**  
**CANDIMALE CREAM**

**1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS**

**1. NAME OF MEDICINAL PRODUCT**

Candimale Cream

**2. QUALITATIVE QUANTITATIVE FORMULA**

<b>ITEM</b>	<b>DRUG NAME</b>	<b>SCALE % W/W</b>	<b>STD QTY PER KG</b>	<b>FUNCTIONS</b>
1.	Miconazole USP	2 %	20.000 g	Active
2.	Ornidazole	2 %	20.000 g	Active
3.	Propylene Glycol BP	5.0 %	50.000 g	Solvent
4.	Cetomacragol 1000 BP	2.0 %	20.000 g	Emulsifying agent
5.	Cetostearyl Alcohol BP	7.0 %	70.000 g	Emulsifying agent
6.	Olivem 700	5.0 %	50.000 g	Emulsifying agent
7.	Hard Paraffin BP	2.0 %	20.000 g	Emulsifying wax
8.	White Soft Paraffin BP	5.0 %	50.000 g	Emulsifying wax
9.	Propylparaben BP	0.01 %	0.100 g	Preservative
10.	Methylparaben BP	0.1 %	1.000 g	Preservative
11.	Butylated Hydroxytoluene BP	0.04 %	0.400 g	Anti-oxidant
12.	Lemon Oil	0.1 %	1.000 g	Flavouring Agent
13.	Orange Oil (5 Folds)	0.3 %	3.000 g	Flavouring Agent
14.	Citric Acid Monohydrate BP	q.s.	Approx. 0.100 g	Buffering Agent

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15.	Purified Water BP	q.s.	Approx 730 g <sup>2</sup> (q. s. to 1000 g)	Vehicle
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**3. PHARMACEUTICAL FORM**

Cream

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

- Preventive measure to avoid transfer of infection.
- Candidial balanitis.
- Balanitis due to Trichomoniasis, other bacterial infections.

**4.2 Posology and method of administration**

As directed by Physician

**4.3 Contraindications**

Documented Hypersensitivity

**4.4 Special warnings and precautions for use**

Before using Candimale Cream, inform your doctor about your current list of medications, over the counter products, allergies, pre-existing diseases, and current health conditions. 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.

**4.5 Fertility, pregnancy and lactation**

NA

**4.6 Effects on ability to drive and use machines**

None

**4.7 Overdose**

Do not exceed the recommended doses. In case of overdosage consult the physician immediately.

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### 5. Pharmacological properties

#### 5.1 Pharmacodynamic properties

Miconazole nitrate is an imidazole antifungal agent and may act by interfering with the permeability of the fungal cell membrane. It possesses a wide antifungal spectrum and has some antibacterial activity..

#### 5.2 Pharmacokinetic properties

**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.

### 6. Pharmaceutical particulars

#### 6.1 List of excipients

Propylene Glycol BP  
Cetomacragol 1000 BP  
Cetostearyl Alcohol BP  
Olivem 700  
Hard Paraffin BP  
White Soft Paraffin BP  
Propylparaben BP  
Methylparaben BP  
Butylated Hydroxytoluene BP  
Lemon Oil  
Orange Oil (5 Folds)  
Citric Acid Monohydrate BP  
Purified Water BP

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**6.2 Incompatibilities**

None

**6.3 Shelf life**

24 months

**6.4 Special precautions for storage**

Store below 30 °C.