Brand Name : MICONAZOLE CREAM **Generic Name :** Miconazole Cream BP 2 % w/w	2021
Module 1 Administrative Information and Product Information **1.5** Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing Information (Summary of Products Characteristics)

1. NAME OF DRUG PRODUCT

1. Name of drug product

Miconazole Cream BP 2% w/w

1.1 (Trade) name of product

MICONAZOLE CREAM

1.2 Strength

Each gram contains:

Miconazole Nitrate BP 2 %w/w

1.3 Pharmaceutical Dosage Form

External application

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

2.1 Qualitative Declaration

Each gram contains:
Miconazole Nitrate BP 2 %w/w

2.2 Quantitative Declaration

Ingredients	Specification	Label Claim	Overages	Qty. / Tab.
ACTIVE				
Miconazole Nitrate	BP	2% w/w	5.00%	20.400 gm
NON ACTIVE				
Propylene Glycol	BP	-	-	96.000 gm
White Soft Paraffin	BP	-	-	60.000 gm
Liquid Paraffin Light	BP	-	-	80.000 gm
Cetomacrogol-1000	BP	-	-	39.000 gm
Cetostearyl Alcohol	BP	-	-	80.000 gm
Chlorocresole	BP	-	-	1000.000 mg
Di Sodium E.D.T.A.	BP	-	-	1000.000 mg
Sodium Metabisulphite.	BP	-	-	1000.000 mg

BP = British Pharmacopoeia.

3. PHARMACEUTICAL DOSAGE FORM

30 GM TUBE

White, homogenous, smooth cream free from grittiness.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Miconazole, sold under the brand name **Monistat** among others, is an antifungal medication used to treat ring worm, pityriasis versicolor, and yeast infections of the skin or vagina. It is used for ring worm of the body, groin (jock itch), and feet (athlete's foot). It is applied to the skin or vagina as a cream or ointment.

Common side effects include itchiness or irritation of the area in which it was applied.[2] Use in pregnancy is believed to be safe for the baby. Miconazole is in the imidazole family of medications. It works by decreasing the ability of fungi to make ergosterol, an important part of their cell membrane. Miconazole was patented in 1968 and approved for medical use in 1971. It is on the World Health Organization's List of Essential Medicines.

4.2 Posology and Method of Administration

Method of administration: External application

4.3 Contraindications

Miconazole is contraindicated for people who use certain drugs that are metabolized by CYP3A4, for the reasons mentioned above:[7]

- drugs that also prolong the QT interval because of potential problems with the heart rhythm
- ergot alkaloids
- statins
- triazolam and oral midazolam
- sulfonamides with a potential to cause hypoglycaemia (low blood sugar)

4.4 Special Warnings and Precautions for Use

Use of topical antibiotics occasionally allows overgrowth of nonsusceptible organisms, including fungi. If this occurs, or if irritation, sensitization, or superinfection develops,

treatment with Gentamicin Sulfate Ointment USP, 0.1% should be discontinued and appropriate therapy instituted.

4.5 Use in Pregnancy and Lactation

Patients are instructed to consult with their physician if they experience severe adverse reaction, they become pregnant or intend to become pregnant or they have any other questions.

4.6 Effects on ability to drive and operate machine

People can drive or use machines after taking **MICONAZOLE CREAM.**

4.7 Overdoses

If irritation develops, use of ointment should be discontinued and appropriate therepy instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmaco-Kinetic Properties

Miconazole Nitrate

After application to the skin, miconazole can be measured in the skin for up to four days, but less than 1% is absorbed into the bloodstream. When applied to the oral mucosa (and possibly also for vaginal use, it is significantly absorbed. In the bloodstream, 88.2% are bound to plasma proteins and 10.6% to blood cells. The substance is partly metabolized via the liver enzyme CYP3A4 and mainly eliminated via the faeces.

Regd. Office & Factory : Plot No. 33, Sector II, The Vasai Taluka Industrial Co-op. Estate Ltd. Gauraipada, Vasai (E), Dist. Thane - 401 208. INDIA.
Tel. : 95250 - 2455801 / 2452714 / 2453525 • Fax : 95250 - 2452074 (0091 - 250 - 2452074) • Email : agog@vsnl.net & agogpharma@rediffmail.com

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Propylene Glycol	BP	96.000 gm
White soft Paraffin	BP	60.000 gm
Liquid Paraffin Light	BP	80.000 gm
Cetomacrogol -1000	BP	39.000 gm
Cetostearyl Alcohol	BP	80.000 gm
Chlorocresole	BP	1000.000 mg
Di Sodium E.D.T.A	BP	1000.000 mg
Sodium Metabisulphite	BP	1000.000 mg

6.2 Incompatibilities

None reported

6.3 Shelf-Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 30°C.
Protect from light.

6.5 Nature and Contents of Container

30 gm/ tube

ANIL K. PANDEY
DIRECTOR

Date :
Director of the manufacturer
(Signature, Full name, Stamp)

AGOG PHARMA LTD. VASAI

ANIL K. PANDEY
DIRECTOR

Date :
Director of applicant company
(Signature, Full name, Stamp)

AGOG PHARMA LTD. VASAI