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TECHNICAL DATA SHEET

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3.0

93799- MICONAZOLE NITRATE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Miconazole Nitrate

Bulk code: 93799

1.2 Synonyms

Miconazoli nitras.

2. DESCRIPTION

Appearance: Crystalline or microcrystalline powder.

Colour: White or almost white.

Odour: Odourless or almost odourless.

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_{18}H_{14}Cl_4N_2O, HNO_3$

CAS: 22832-87-7

Molecular weight: 479.1 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications in analysis report.


Solubility: It is soluble in dimethylsulphoxide, dimethylformamide and methanol, slightly soluble in alcohol, propylene glycol and chloroform and practically insoluble in ether, water.

Melting point: 178–184°C, with decomposition.

5. PROPERTIES/USES

Miconazole nitrate is an agent with fungistatic action, pertaining to the group of imidazolides, which acts by altering the permeability of the fungal membrane by inhibiting the synthesis of ergosterol, providing broad-spectrum activity, including against dermatophytes and yeasts, such as *Candida*. It is also active against *Trichomonas vaginalis*.

It is used topically to treat fungal infections of the skin and nails, such as skin candidiasis, athlete's foot, ringworm of the body, crural region, versicolor, head and beard. It is also used topically in acne vulgaris therapy.

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Vaginally, it is used for vaginitis caused by Candida and Trichomonas.

6. DOSAGE

Topically:

- In the form of creams, lotions and powders at a concentration of 2%, applied twice a day. It is usually associated with keratolytics or other antifungal agents. For anti-acne treatments, it is usually associated with 5% benzoyl peroxide.

Vaginally:

- As a 2% cream, given at 5–10 g once daily, for 1–2 weeks, or as vaginal pessaries or tablets at a dose of 100 mg.

7. REMARKS

STORAGE:

Store at room temperature ($25\pm 2^{\circ}\text{C}$), in a cool, dry place, away from sunlight, in a tightly closed container.

8. BIBLIOGRAPHY

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).