1.5 Product information

1.5.1 Prescribing information (Summary of product characteristics)

1. NAME OF THE MEDICINAL PRODUCT

Miconazole Nitrate Vaginal Cream USP 2% W/W (MICONA VAGINAL CREAM)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Miconazole Nitrate Vaginal Cream USP 2% w/w (MICONA VAGINAL CREAM)

Composition:

Miconazole Nitrate BP…. 2% w/w

Preservative:

Benzoic Acid BP…… 0.2% w/w

In cream base…….. q. s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vaginal Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Vaginal and vulvovaginal infections caused by Candida (moniliasis) or other sensitive fungi.
- Vaginal mycoses secondarily infected by Gram-positive bacteria.
- Mycotic baJanitis (male partner).

- Leukorrhea with itching and burning sensation of the vulva, when candidal or bacterial infection is suspected.

4.2 Posology and method of administration

Every evening for 1 week (a full applicator) is inserted deeply into the vagina.

The entire treatment should be completed even when the symptoms disappear.

Treatment should be continued during menstruation.

To open the tube, unscrew the cap and use the back of the cap to pierce the aluminium sealing strip, then fit the applicator to the top of the tube.

- Press the tube end to bring the cream into the applicator. If the piston shows resistance, pull gently. Unless otherwise prescribed by the physician, the applicators should be completely filled.
- Remove the applicator from the tube and close the tube instantly with the cap.
- While lying down, knees bent and spread apart, insert the filled applicator into vagina as deeply as possible. Press piston completely, then remove applicator without pulling the piston.
- The applicator should be kept clean. Wash it carefully with soap and warm water.
- Preserve the applicator in a case or other clean packing.

4.3 Contraindications

Micona Vaginal Cream is contraindicated in patients with known hypersensitivity to miconazole.

Caution should be exercised when using Micona Vaginal Cream during pregnancy & lactation.

4.4 Special warnings and precautions for use

Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with miconazole formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.

Miconazole Nitrate Vaginal Cream USP 2% W/W (MICONA VAGINAL CREAM) must not come into contact with the mucosa of the eyes.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the limited systemic availability after vaginal application, interactions are unlikely to occur. However in patients using oral anticoagulants such as Warfarin, caution should be exercised and anti-coagulant effect should be monitored.

4.6 Pregnancy and lactation

Pregnancy

Miconazole Nitrate Vaginal Cream USP 2% W/W (MICONA VAGINAL CREAM) Cream applied topically is minimally absorbed into the circulation (bioavailability < 1%). Although there is no evidence that miconazole is embryotoxic or teratogenic in animals, potential hazards of prescribing Miconazole Nitrate Vaginal Cream USP 2% W/W (MICONA VAGINAL CREAM) during pregnancy should always be weighed against the expected therapeutic effects.

Lactation

Topically applied miconazole is minimally absorbed into the systemic circulation, and it is not known whether miconazole is excreted in human breast milk. Caution should be exercised when using topically applied miconazole products during lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Micona Vaginal Cream is well-tolerated.

Most frequently adverse reactions were local irritation, pruritus and burning sensation especially at the start of the treatment. Complaints of pelvic cramping, skin rash have also been reported.

4.9 Overdose

Symptoms and Signs

Cutaneous use: Excessive use can result in skin irritation, which usually disappears after discontinuation of therapy.

Treatment

Accidental ingestion: Miconazole Nitrate Vaginal Cream USP 2% W/W (MICONA VAGINAL CREAM) is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Micona Vaginal Cream contains miconazole nitrate, the broad spectrum antimycotic agent. This agent has a potent fungicidal activity against the common pathogenic fungi including Candida species (e.g. C. albians, C. glabrata and related species), yeasts, yeast-like organisms and dermatophytes such as Trichophyton, Microsporum and Epidermophyton species. Micona exerts its fungicidal effect through inhibition of ergosterol synthesis resulting in disruption of the integrity of cell membranes of sensitive fungi.

Micona also possesses bactericidal action against Gram-positive bacilli and cocci.

Because of this broad spectrum activity, Micona is particularly useful in mixed vulvovaginal infections. Clinical studies have also evidenced that miconazole nitrate is significantly more effective than nystatin in vulvovaginal candidiasis with rapid relief of symptoms such as burning sensation, pruritus and leukorrhea. The use of Micona Vaginal Cream is considered safe even during pregnancy as the released miconazole nitrate acts topically with poor absorption from the vagina.

5.2 Pharmacokinetic properties

Absorption: Miconazole remains in the skin after cutaneous application for up to 4 days. Systemic absorption of miconazole is limited, with a bioavailability of less than 1% following cutaneous application of miconazole. Plasma concentrations of miconazole and/or its metabolites were measurable 24 and 48 hours after application. Systemic absorption has also been demonstrated after repeated application of miconazole to infants with nappy rash. Plasma levels of miconazole were undetectable or low in all infants.

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 over a four-day post-administration period. Smaller amounts of unchanged drug and metabolites also appear in urine.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of local irritation, single and repeated dose toxicity, genotoxicity, and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Myristate BP, Cetostearyl Alcohol BP, Cetomacrogol 1000 BP, Light Liquid Paraffin BP, Butylated Hydroxyanisole BP, Butylated Hydroxytoluene BP, Disodium EDTA BP, Benzoic Acid BP, Polysorbate 60 BP, Propylene Glycol BP, Glycerin BP, Phosphoric Acid BP, Disodium Hydrogen Phosphate Dodecahydrate BP, Simethicone Emulsion 30% USP, Purified Water BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

A tube containing 40 g of the cream with an applicator.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

Centaur Pharmaceuticals Pvt. Ltd.

8. MARKETING AUTHORISATION NUMBER(S)

No. 528 (70)/MFG/DFDA/2018/4568

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09.03.2018

10. DATE OF REVISION OF THE TEXT

June 2019.