



# MECOZALEN

(Vaginal Suppositories 400 mg, Vaginal Cream 2%)  
Miconazole Nitrate



#### **CHEMICAL COMPOSITION:**

Each 1 g MECONAZOL vaginal cream contains: 20 mg Miconazole Nitrate.  
Each MÉCOZALEN vaginal suppository contains: 400 mg Miconazole Nitrate.

#### **Excipients:**

Vaginal cream: Glycerol Monostearate, Cetostearyl Alcohol, Emulgine B2, Vaseline, Liquid Paraffin, Glycerin, Nipazole Na, Nipagin Na, Sodium Hydraxide, Deionized Water.  
Vaginal suppositories: Hydrated vegetable oil, Aerosil.

#### **MECHANISM OF ACTION:**

Miconazole combines a potent antifungal activity against common dermatophytes and yeasts with an antibacterial activity against certain gram-positive bacilli and cocci. In general, miconazole exerts a very rapid effect on pruritus, a symptom that frequently accompanies dermatophyte and yeast infections.

#### **PHARMACOKINETICS:**

**Absorption:** Miconazole persists in the vagina for up to 72 hours after a single dose. Systemic absorption of miconazole after intravaginal administration is limited and the bioavailability of 1 to 2% following intravaginal administration of a 1200 mg dose.

**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.

#### **INDICATIONS:**

- For the treatment of mycotic vulvovaginitis and superinfections due to gram-positive bacteria.
- treats vaginal yeast infections
- relieves external itching and irritation due to a vaginal yeast infection

#### **DOSAGE AND METHOD OF ADMINISTRATION:**

##### **Vaginal cream:**

Adults (aged 18 years and older): Administer the contents of one applicator (about 5 g of cream) once daily deeply into vagina for 10 – 14 days or twice daily for 7 days.

For vulvitis the cream should be applied topically twice daily. Continue the course of treatment even after pruritus and leukorrhoea have disappeared or menstruation begins.

**Pediatrics (aged less than 18 years):** The safety and efficacy of miconazole vaginal cream in children and adolescents has not been studied.

##### **Vaginal Suppositories:**

Adults and children 12 years of age and over: insert 1 Suppository into the vagina at bedtime for 3 nights in a row.

**Pediatrics (aged less than 12 years):** ask a doctor.

Before prescribing another course of therapy, the diagnosis should be reconfirmed by smears and/or cultures to rule out other pathogen.

#### **CONTRAINDICATIONS:**

Known hypersensitivity to miconazole nitrate or other imidazole derivatives or any of the excipients.

#### **WARNINGS AND PRECAUTIONS:**

- Severe hypersensitivity reactions, including anaphylaxis and angioedema, have been reported during treatment with miconazole vaginal cream and with other miconazole formulations. If a reaction suggesting hypersensitivity or irritation should occur, the treatment should be discontinued.
- Appropriate therapy is used when the sexual partner is also infected.
- Miconazole vaginal cream does not stain skin or clothes.
- Vaginal anti-infective preparations may decrease the effectiveness of latex contraceptive agents. Therefore it should not be used concurrently with a latex condom or latex diaphragm.

- Vaginal products should be avoided

Check with the doctor before use if vaginal yeast infections are frequent (such as once a month or 3 in 6 months), it could be serious underlying medical cause, including (diabetes or a weakened immune system) or if the vaginal itching and discomfort is for the first time.

#### **Stop use and check with the doctor if**

- Symptoms do not get better in 3 days
- Symptoms last more than 7 days
- If the patient gets a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge, it could be more serious condition.

#### **Laboratory Tests:**

If there is a lack of response to Miconazole Vaginal Suppositories, appropriate microbiological studies should be repeated to confirm the diagnosis and rule out other pathogens.

#### **DRUG INTERACTION:**

- Miconazole administered systemically is known to inhibit CYP3A4/2C9. Due to the limited systemic availability after vaginal application, clinically interactions occur very rarely.
- In patients on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be monitored because bleeding or bruising may occur
- The effects and side effects of other drugs metabolized by CYP2C9 (e.g. oral hypoglycemics and phenytoin) and also CYP3A4 (e.g., simvastatin and lovastatin and calcium channel blockers such as dihydropyridines and verapamil), when co-administered with miconazole, can be increased and caution should be exercised.

#### **Pregnancy and lactation:**

**Pregnancy:** Although intravaginal absorption is limited, miconazole should be used in the first trimester of pregnancy only if the potential benefit outweigh the possible risks.

**Breastfeeding:** It is not known whether miconazole nitrate is excreted in human milk. Caution should be exercised when using miconazole during breastfeeding.

#### **ADVERSE REACTIONS:**

**Very common:** Genital pruritis, vaginal burning sensation, vulvovaginal discomfort.

**Common:** Rash, Dysmenorrhea.

**Uncommon:** pruritis, rash, urticaria, headaches, itching or irritation, cramping.

**Rare:** hives.

#### **OVERDOSE:**

**Symptoms:** miconazole vaginal cream and ovules are intended for local application and not for oral use. In case of accidental ingestion, no problems are expected.

**Treatment:** In the event of accidental ingestion of large quantities, appropriate supportive care should be used.

#### **STORAGE CONDITIONS:**

- Vaginal cream:** Store at temperature between (15-25) °C
- Vaginal suppositories:** Store at temperature between (15-25) °C.
- Keep out of reach of children.

#### **PACKAGE:**

##### **Vaginal cream:**

Aluminium tube contains 70 g MECOZALEN vaginal cream with an applicator/carton box.

##### **Vaginal Suppositories:**

Carton MECOZALEN box contains 3 vaginal Suppositories.

Carton MECOZALEN box contains 6 vaginal Suppositories.

#### **\* THIS IS A MEDICAMENT \***

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

( Council of Arab Ministers )

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