

# MICONAZOLE NITRATE GEL 2.0% w/w

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## Fungitop

### COMPOSITION:

Miconazole Nitrate IP 2.0% w/w  
in a water soluble gel base.

### CHEMISTRY:

It is chemically described as (RS)-1-(2-(2,4-Dichlorobenzyloxy)-2-(2,4-dichlorophenyl)ethyl)-1H-imidazole

### PHARMACOLOGICAL CATEGORY:

Imidazole and triazole derivatives

### PHARMACOLOGY:

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.

### PHARMACOKINETICS:

**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.

### INDICATIONS:

Fungal skin infections

Fungal nail infections

Superficial sites of infection in vaginal and vulval candidiasis

Vulvitis

### CONTRAINDICATIONS:

Fungitop is contraindicated in individuals with a known hypersensitivity to miconazole/miconazole nitrate, other imidazole derivatives or to any of its excipients.

### SIDE EFFECTS/ADVERSE EFFECTS:

#### General side-effects:

#### Common or very common

Nausea; rash; vomiting

#### Specific side-effects:

Frequency not known

*With topical use:* burning sensation; erythema; hypersensitivity reactions; itching

*With topical use or vaginal use:* occasional local irritation

Side-effects, further information

With topical use: Treatment should be discontinued if side effects are severe.

### PRECAUTIONS AND WARNINGS:

#### General cautions:

Avoid in Acute porphyrias: The acute porphyrias (acute intermittent porphyria, variegate porphyria, hereditary coproporphyria, and 5-aminolaevulinic acid dehydratase deficiency porphyria) are hereditary disorders of haem biosynthesis; they have a prevalence of about 1 in 75 000 of the population.

Great care must be taken when prescribing for patients with acute porphyria, since certain drugs can induce acute porphyric crises. Since acute porphyrias are hereditary, relatives of affected individuals should be screened and advised about the potential danger of certain drugs.

#### Specific cautions:

*With topical use:* contact with eyes and mucous membranes should be avoided

*With vaginal use:* avoid intravaginal preparations (particularly those that require use of an applicator) in young girls who are not sexually active, unless there is no alternative (in children)

### DRUG INTERACTIONS:

Interactions of miconazole apply to the oral gel formulation, as a sufficient quantity can be absorbed to cause systemic effects. Systemic absorption from intravaginal and topical formulations might also occur.

Miconazole has the following interaction information:

acenocoumarol	Miconazole greatly increases the anticoagulant effect of acenocoumarol. MHRA advises avoid unless INR can be monitored closely; monitor for signs of bleeding.
alfentanil	Miconazole is predicted to increase the exposure to alfentanil. Manufacturer advises use with caution and adjust dose.
alitretinoin	Miconazole is predicted to increase the exposure to alitretinoin. Manufacturer advises adjust alitretinoin dose.
alprazolam	Miconazole is predicted to increase the exposure to alprazolam. Manufacturer advises use with caution and adjust dose.
amlodipine	Miconazole is predicted to increase the exposure to amlodipine. Manufacturer advises use with caution and adjust dose.
atazanavir	Miconazole is predicted to increase the concentration of atazanavir. Manufacturer advises use with caution and adjust dose.
atorvastatin	Miconazole potentially increases the exposure to atorvastatin.
buspirone	Miconazole is predicted to increase the concentration of buspirone. Manufacturer advises use with caution and adjust dose.
busulfan	Miconazole is predicted to increase the concentration of busulfan. Manufacturer advises use with caution and adjust dose.
carbamazepine	Miconazole increases the risk of carbamazepine toxicity when given with carbamazepine. Manufacturer advises monitor and adjust dose.
ciclosporin	Miconazole increases the concentration of ciclosporin. Manufacturer advises monitor and adjust dose.
cilostazol	Miconazole is predicted to increase the exposure to cilostazol. Manufacturer advises use with caution and adjust dose.
clevidipine	Miconazole is predicted to increase the exposure to clevidipine. Manufacturer advises use with caution and adjust dose.
cobimetinib	Miconazole is predicted to increase the exposure to cobimetinib.
darunavir	Miconazole is predicted to increase the concentration of darunavir. Manufacturer advises use with caution and adjust dose.
disopyramide	Miconazole is predicted to increase the exposure to disopyramide. Manufacturer advises use with caution and adjust dose.
docetaxel	Miconazole is predicted to increase the concentration of docetaxel. Manufacturer advises use with caution and adjust dose.
ergometrine	Miconazole is predicted to increase the exposure to ergometrine. Manufacturer advises avoid.
ergotamine	Miconazole is predicted to increase the exposure to ergotamine. Manufacturer advises avoid.
felodipine	Miconazole is predicted to increase the exposure to felodipine. Manufacturer advises use with caution and adjust dose.
flavastatin	Miconazole is predicted to increase the exposure to flavastatin.
fosamprenavir	Miconazole is predicted to increase the concentration of fosamprenavir. Manufacturer advises use with caution and adjust dose.
fosphenytoin	Miconazole increases the risk of phenytoin toxicity when given with fosphenytoin. Manufacturer advises monitor and adjust dose.
glibenclamide	Miconazole is predicted to increase the exposure to glibenclamide. Manufacturer advises use with caution and adjust dose.
gliclazide	Miconazole is predicted to increase the exposure to gliclazide. Manufacturer advises use with caution and adjust dose.
glimepiride	Miconazole is predicted to increase the exposure to glimepiride. Manufacturer advises use with caution and adjust dose.

glipizide	Miconazole is predicted to increase the exposure to glipizide. Manufacturer advises use with caution and adjust dose.
isradipine	Miconazole is predicted to increase the exposure to isradipine. Manufacturer advises use with caution and adjust dose.
lacidipine	Miconazole is predicted to increase the exposure to lacidipine. Manufacturer advises use with caution and adjust dose.
lercanidipine	Miconazole is predicted to increase the exposure to lercanidipine. Manufacturer advises use with caution and adjust dose.
lopinavir	Miconazole is predicted to increase the concentration of lopinavir. Manufacturer advises use with caution and adjust dose.
methylprednisolone	Miconazole is predicted to increase the concentration of methylprednisolone. Manufacturer advises monitor and adjust dose.
midazolam	Miconazole is predicted to increase the exposure to intravenous midazolam. Manufacturer advises use with caution and adjust dose.
	Miconazole is predicted to increase the exposure to oral midazolam. Manufacturer advises avoid.
mizolastine	Miconazole is predicted to increase the exposure to mizolastine. Manufacturer advises avoid.
nicardipine	Miconazole is predicted to increase the exposure to nicardipine. Manufacturer advises use with caution and adjust dose.
nifedipine	Miconazole is predicted to increase the exposure to nifedipine. Manufacturer advises use with caution and adjust dose.
nimodipine	Miconazole is predicted to increase the exposure to nimodipine. Manufacturer advises use with caution and adjust dose.
phenindione	Miconazole greatly increases the anticoagulant effect of phenindione.
phenytoin	Miconazole increases the risk of phenytoin toxicity when given with phenytoin. Manufacturer advises monitor and adjust dose.
pimozide	Miconazole is predicted to increase the exposure to pimozide. Manufacturer advises avoid.
reboxetine	Miconazole is predicted to increase the concentration of reboxetine. Manufacturer advises use with caution and adjust dose.
rifabutin	Miconazole is predicted to increase the concentration of rifabutin. Manufacturer advises use with caution and adjust dose.
ritonavir	Miconazole is predicted to increase the concentration of ritonavir. Manufacturer advises use with caution and adjust dose.
saquinavir	Miconazole is predicted to increase the concentration of saquinavir. Manufacturer advises use with caution and adjust dose.
sildenafil	Miconazole is predicted to increase the exposure to sildenafil. Manufacturer advises use with caution and adjust dose.
simvastatin	Miconazole is predicted to increase the exposure to simvastatin. Manufacturer advises avoid. severity: Severe evidence: Theoretical
sirolimus	Miconazole is predicted to increase the concentration of sirolimus. Manufacturer advises monitor and adjust dose.
tacrolimus	Miconazole is predicted to increase the concentration of tacrolimus. Manufacturer advises monitor and adjust dose.
Tipranavir	Miconazole is predicted to increase the concentration of Tipranavir. Manufacturer advises use with caution and adjust dose.
tobramycin	Miconazole potentially decreases the exposure to tobramycin.
tolbutamide	Miconazole is predicted to increase the exposure to tolbutamide. Manufacturer advises use with caution and adjust dose.

verapamil	Miconazole is predicted to increase the exposure to verapamil. Manufacturer advises use with caution and adjust dose.
vinblastine	Miconazole is predicted to increase the concentration of vinblastine. Manufacturer advises use with caution and adjust dose.
vincristine	Miconazole is predicted to increase the concentration of vincristine. Manufacturer advises use with caution and adjust dose.
vindesine	Miconazole is predicted to increase the concentration of vindesine. Manufacturer advises use with caution and adjust dose.
vinflunine	Miconazole is predicted to increase the concentration of vinflunine. Manufacturer advises use with caution and adjust dose.
vinorelbine	Miconazole is predicted to increase the concentration of vinorelbine. Manufacturer advises use with caution and adjust dose.
warfarin	Miconazole greatly increases the anticoagulant effect of warfarin. MHRA advises avoid unless INR can be monitored closely; monitor for signs of bleeding.

#### PREGNANCY AND LACTATION:

**With topical use:** Absorbed from the skin in small amounts; manufacturer advises caution.

**Lactation:** Manufacturer advises caution—no information available.

#### DOSAGE AND ADMINISTRATION:

Fungal skin infections

To the skin

**Adult:** Apply twice daily continuing for 10 days after lesions have healed.

**Child:** Apply twice daily continuing for 10 days after lesions have healed.

**Neonate:** Apply twice daily continuing for 10 days after lesions have healed.

Fungal nail infections

To the skin

**Adult:** Apply 1–2 times a day.

**Child:** Apply 1–2 times a day.

Superficial sites of infection in vaginal and vulval candidiasis

Vulvitis

By vagina

**Adult**

Apply twice daily, apply to the anogenital area.

#### DIRECTIONS FOR ADMINISTRATION

Gently apply gel on the affected areas until it disappears.

#### OVERDOSAGE AND TREATMENT:

**Symptoms**

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

**Treatment**

Miconazole nitrate is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care

#### STORAGE CONDITIONS:

Store below 30°C. Keep out from reach of children.

#### PRESENTATION:

15 g per Aluminium tube

#### DATE OF PUBLICATION:

May 2018

#### DATE OF REVISION:

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Manufactured by :



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