

**DERMAZOL PLUS GEL**  
(Antifungal - Anti-inflammatory - Antipruritic)

**Active Ingredients:**

Miconazole Nitrate ..... 2%/w/w  
Hydrocortisone Acetate ..... 1%/w/w

**Presentations:**

Tubes of 10g and 20g and box of 10g x 50 tubes.

**Product Descriptions:**

White to off white gel.

**Pharmacology:**

Miconazole is a broad-spectrum antifungal and is effective against common dermatophytes and yeasts. It has antibacterial activity against certain gram-positive bacilli and cocci. It inhibits the biosynthesis of ergosterol in fungi and changes the composition of other lipid components in the membrane, resulting in fungal cell necrosis. In general, Miconazole exerts a very rapid effect on pruritus, a symptom that frequently accompanies dermatophyte and yeast infections.

Hydrocortisone is absorbed from sites of local application. When administration is chronic or large areas of skin are involved, the absorption may be sufficient to cause systemic effects, including adrenocortical suppression, systemically; Hydrocortisone disappears rapidly from the circulation via hepatic metabolism. The liver converts Hydrocortisone to inactive acidic compounds. These compounds are easily excreted by the kidneys.

Following topical application of Miconazole, 88.2% is bound to plasma proteins and 10.6% bound to red blood cells. The small amount of absorbed Miconazole is then eliminated predominantly in faeces as both unchanged drug and metabolites.

Topical application of Hydrocortisone is metabolized in the skin and while systemic Hydrocortisone is metabolized by the liver to inactive metabolites. These inactive metabolites, as well as a small portion of unchanged drug, are excreted in the urine. The biological half-life of Hydrocortisone is 8 to 12 hours.

**Indications:**

For the topical treatment of infections of the skin by dermatophytes of *Candida spp.* in which inflammatory symptoms are prominent. In view of Dermazol antibacterial effect on gram-positive bacteria, the product may also be used for mycotic affections with bacterial superinfection.

**Directions of Use:**

**Dermazol Plus Gel** should be applied topically to the lesion (or more, according to its size) 1 to 2 times daily. It should be rubbed in gently with your finger until it has been completely penetrated into the skin. This dosage applies to both adults and children.

**Use in infants:**

In infants, long term continuous topical corticosteroid therapy should be avoided.

**Use in elderly:**

Natural thinning of the skin occurs in the elderly; hence corticosteroids should be used sparingly and for short periods of time. If after 7 days of treatment no improvement has occurred, cultural isolation of the infecting organism should be followed by appropriate local or systemic antimicrobial therapy.

**Symptoms and Treatment of Overdose:**

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

No specific antidote is available. In the event of accidental ingestion, the patient should be observed and treated symptomatically.

**Contraindications:**

Do not use if hypersensitivity to Miconazole and Hydrocortisone. Contraindicated in tuberculous condition of the skin, herpes simplex, vaccinia and varicella.

**Precautions:**

As with any topical corticosteroid, care is advised with infants and children when Dermazol Plus Gel is to be applied to extensive surface areas or under occlusive dressings including baby napkins; similarly, application to the face should be avoided. In infants, long term continuous topical corticosteroid therapy should be avoided. Adrenal suppression can occur even without occlusion.

For external use only. Avoid in contact with eyes, nose and mouth. Not to be taken.

Do not use under occlusion unless under medical supervision.

Application should be sparingly and confined to affected areas only.

Should not be used in bacterial skin infections without suitable concomitant antimicrobial therapy.

In patients on warfarin, caution should be exercised and the anticoagulant effect should be monitored (see interactions).

If symptoms persist, please consult a doctor.

**Use in Pregnancy and Lactation:**

Use in pregnancy should not be extensive, unless the expected benefit outweighs the potential risk.

Use in lactation is not recommended. However any excretion into breast milk is likely to be low.

**Undesirable Effects:**

Occasionally, **Dermazol Plus Gel** may cause skin rash, irritation and blistering in some sensitive people.

Local atrophy and striae of the skin may occur on prolonged use.

**Interactions with Other Medicaments:**

Miconazole administered systemically is known to inhibit CYP2C9 enzyme system. Due to the limited systemic availability after topical application, clinically relevant interactions occur very rarely. In patients on warfarin which is subjected to metabolism by CYP2C9, caution should be exercised and the anticoagulant effect should be monitored (see Warnings and Special Precautions).

Do not use any other skin products on the affected area without consulting your doctor or health professional.

**Storage:**

Store below 30°C. Protect from light. Keep cap tightly closed.

Keep out of reach of children.

Jauhkan daripada capaian kanak-kanak.

**Shelf Life:**

2 years from the date of manufacture.

Manufacturer and Product Registration Holder

**WINWA MEDICAL SDN. BHD.**

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**MAL08042471AZ**

Date of Revision: 08 July 2025

A.EDG-1.07

Size: 75mm x 125mm  
■ Dark Blue (Pantone 2767U)

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| Checked by  |  |
| Approved by |  |