

Mycosept

Dermal Cream



Composition:

Each 1g of Mycosept Dermal Cream contains:

Miconazole Nitrate 20 mg.

Pharmacological Classification:

Anti-fungal.

Intended Use (Common Use of the Drug):

Treatment of fungal skin infections.

Mechanism of Action:

Miconazole possesses an antifungal activity against the common dermatophytes and yeasts as well as an antibacterial activity against certain gram-positive bacilli and cocci. Its activity is based on the inhibition of the ergosterol biosynthesis in fungi and the change in the composition of the lipid components in the membrane, resulting in fungal cell necrosis.

Pharmacokinetics:

Absorption: There is little absorption through skin or mucous membranes when Mycosept 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:

Use this medicine exactly as described in this leaflet or as directed by your doctor or pharmacist, consult your doctor if you are not sure.

- Treatment of fungal infections of the skin and nails:
- Treatment of athlete's foot, tinea pedis, and ringworm of the body.
- Relieves itching, burning, cracking, scaling and discomfort which accompany these conditions.
- Treatment of infections caused by Gram-positive bacteria.

Contraindications:

This medicine should not be used if you are hypersensitive to the active substance or any of the excipients.

- In patient has hypersensitivity to the active ingredient or to the excipients.
- In patients who never had a vaginal yeast infection diagnosed by a doctor.

Side Effects:

Like all medicines, this one can cause side effects, although not everyone experiences them.

Uncommon: Skin irritation (e.g. burning sensation, redness, warmth, itching) at the application site.

Warnings & Precautions:

- Avoid using Mycosept in children under two years of age unless under the supervision of a doctor.
- Mycosept for external use only.
- When using Mycosept avoid contact with eyes.

Drug and Food Interactions:

Tell your doctor or pharmacist if you are using, have recently used or might use any other drugs, and for how long you will be using the drug.

- Miconazole is unlikely to be absorbed through the skin in sufficient amounts to significantly affect other medicines that you are taking by mouth.

- If you are taking warfarin, there is a very small chance that miconazole absorbed from this cream may enhance the effect of the warfarin.

Pregnancy & Lactation & Fertility:

Pregnancy: Mycosept should be used with caution during pregnancy, and only if the expected benefit to the mother is greater than any possible risk.

Lactation: It should be used with caution by breastfeeding mothers, and only if the expected benefit to the mother is greater than any possible risk to the baby. If you do use Mycosept cream while breastfeeding, you should not apply it to the skin of the breasts shortly before giving a feed, to avoid it being ingested by the nursing infant.

Fertility: Its effect on fertility has not been studied after topical application in humans.

Effects on ability to drive and use machines:

Mycosept cream has no influence on the ability to drive and use machines.

Method of use:

Use this drug exactly as your doctor or pharmacist has prescribed it. Ask your doctor if you are not sure.

- Fungal skin infections: Apply a small amount of cream to the lesions twice daily. Rub the cream into the skin with your finger until it penetrates completely. The duration of treatment ranges from 2 to 6 weeks depending on the location and severity of the lesion. Treatment should be continued for at least one week after all signs and symptoms have disappeared.

- Fungal nail infections: Apply the cream once or twice daily to the lesions. Treatment should be continued for 10 days after all lesions have disappeared to prevent relapse. Inform your doctor or pharmacist if you forget to apply the Dermal Cream and before stopping its use.

Overdoses/Toxicity/methods of treatment:

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

Treatment: Mycosept cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, use appropriate supportive care.

Physical Properties:

White to off-white, smooth, uniform, free from foreign matter Cream.

Storage Conditions:

Store at a temperature below 25° C.

Keep out of reach of children.

Keep tube tightly closed.

Packaging:

Each Mycosept Dermal Cream carton box contains Aluminium Tube of 30 g.

*A medication is a product which affects your health, and it's consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist experts in medicine, its benefits and risks.
- Do not repeat the same prescription without consulting your doctor.
KEEP THE MEDICATIONS OUT OF REACH OF CHILDREN
Council of Arab Health Ministers- Union of Arab Pharmacies

Reva Pharma for Pharmaceutical Industries - Idlib - Syria

PO1413 / R02

کریم جلدي

التركيب:

مضاد فطري.

الآلية التأثيرية:

الحرانك الدوائية:

التوزيع: يرتبط الميكونازول الممتص ببروتينات البلازما

الاستقلاب والاطراح: يتم التخلص من الكميات

الاستجابات:

- يخفف من الحكة، الحرقه، التقيشير والشعور بعدم الراحة

- علاج الالتهابات الناتجة عن الإصابة بالجراثيم إيجابية الغر

يمنع استخدام هذا الدواء

التأثيرات الجانبية:

تأثيرات غير شائعة: تهيج الجلد (الإحساس بالحرق، احمرار،

- نجيب استعمال مايكروسييب عند الأطفال تحت عمر السنين إلا

التداخلات الدوائية والغذائية.

- من غير المحتمل أن يمتص الميكونازول عبر الجلد بكميات تكفي

الحمل والإرضاع والخصوبة:

الإرضاع: يجب استخدامه بحذر من قبل الأمهات و فقط عندما

يُطبق على جلد السليبي بقشره قصيره قبل ابرصاع لتجلب ابداعه

التأثيرات على القدرة على القيادة واستخدام الآلات:

طريقة الاستعمال:

- الانتانات الفطرية الجلدية: ضع القليل من الكريم على الآفات

وشدتها. يجب الاستمرار في العلاج لمدة اسبوع واحد على الأقل

مرتين يوميا على الإفات. يجب استمرار العلاج لمدة ١٠ أيام بعد

فقط الحارصة/السيمية/طرق العلاج:

العلاج: كرم ماكنو سببت مخصص، للاستخدام الحدي، وليس

الخصائص الفيزيائية:

شروط التخزين:

يحفظ الأنبوب محكم الإغلاق.

المليوم سعه ١٠ ع.

الذي صرفها لك ، فالطبيب والصيداني هما الخبيران في الدواء وينفعه وضرره
لا تكرر صرف الدواء بدون وصفة طبية.

الدواء مستحضر يؤثر على صحتك واستعماله خلافاً للتعليمات يمنعك للضرر
اتبع بدقة وصفة الطبيب وطريقة الاستعمال المخصوص : لأنها وتعليمات الصيدلي
الذي صرفها لك ، فالطبيب والصيدلي هما اللذين ان في الدواء وينفعه وضروبه
لا تكرر صرف الدواء بدون وصفة طبية
لا تتركه الاذوية بمقتول أيدي الأطفال
مجلس وزراء الصحة العرب واتحاد الميادلة العرب