

Miconazole 2% cream

This information is a summary only. It does not contain all information about this medicine. If you would like more information about the medicine you are taking, check with your doctor or other health care provider. No rights can be derived from the information provided in this medicine leaflet.

Therapeutic indications

For the treatment of mycotic infections of the skin and nails and superinfections due to Gram-positive bacteria.

Posology and method of administration

Route of administration:

Cutaneous use.

Recommended dosage:

For all ages:

Skin infections: Apply the cream twice daily to the lesions. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

Nail infections: Apply the cream once or twice daily to the lesions. Treatment should be prolonged for 10 days after all lesions have disappeared to prevent relapse.

Contraindications

Miconazol Cream is contraindicated in individuals with a known hypersensitivity to miconazole or another ingredient in this product.

Miconazol Cream must not come into contact with the eyes.

If a reaction suggesting sensitivity or irritation should occur, the treatment should be discontinued.

In patient on oral anticoagulants, such as warfarin, caution should be exercised and anticoagulant effect should be mentioned.

Pregnancy

In animals miconazole nitrate has shown no teratogenic effects but is foetotoxic at high oral doses. Only small amounts of miconazole nitrate are absorbed following topical administration. However, as with other imidazoles, miconazole nitrate should be used with caution during pregnancy.

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.

Effects on ability to drive and use machines

Not applicable

Overdose/Symptoms

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

Treatment

Miconazol Cream is intended for cutaneous use, not for oral use. If accidental ingestion of large quantities of the product occurs, an appropriate method of gastric emptying may be used if considered necessary.

Special precautions for storage

Do not store above 25°C.