

Batrafen® Nail Lacquer

Active ingredient: *Ciclopirox*

sanofi aventis

This package insert is continually updated: please read carefully before using a new pack!

Composition

Each gramme of Batrafen Nail Lacquer contains, as active ingredient, 80 mg ciclopirox. Excipients: Copolymer of methylvinylether and maleic acid monobutyl ester, ethyl acetate, 2-propanol.

Properties

Batrafen Nail Lacquer has been specially developed for the treatment of fungal infections of the nails. The active ingredient ciclopirox penetrates the nail plate and reaches the fungal pathogen in as short a time as 48 hours after application. Ciclopirox has a fungicidal action against all relevant pathogens responsible for fungal infections of the nails.

Indications

Fungal infections of the nails.

Contraindications

Owing to a lack of clinical experience, Batrafen Nail Lacquer is not indicated for use in children.

Precautions

If the application of Batrafen Nail Lacquer is considered during pregnancy or lactation, it should only be used where absolutely essential.

Adverse reactions

In a few exceptional cases, redness and scaling have been observed where Batrafen Nail Lacquer has come in contact with the skin adjacent to the nail.

If you notice any adverse reactions, please consult a physician.

Dosage and administration

Before applying Batrafen Nail Lacquer for the first time, as much as possible of the affected nail material should be removed, e.g. with scissors, and the remaining diseased nail roughened with a nail file.

Unless otherwise directed, Batrafen Nail Lacquer is applied to the diseased nail in a thin layer every other day for the first month. This ensures that the nail is saturated with the active ingredient. Application may be reduced to not less than twice weekly in the second month of treatment, and to once weekly from the third month of treatment onwards.

Throughout the application period, the entire coating of lacquer is taken off once a week with a commercial nail varnish remover. During this process, as much as possible of the affected nail material should again be removed, using a nail file. If the coating of lacquer is damaged in the meantime, it is sufficient to paint over the chipped areas again with Batrafen Nail Lacquer.

The duration of application depends on the severity of the infection, but a period of six months' treatment should not be exceeded.

Special notes

To prevent the solution from drying up, the cap must be firmly screwed down after use. To prevent the screw cap from sticking to the bottle, avoid spilling solution on the screw thread.

Storage

Protect from light (e.g. leave the bottle in the carton, or replace it in the carton after use). Batrafen Nail Lacquer can be stored at room temperature. Once the bottle has been opened, Batrafen Nail Lacquer is stable for at least 6 months if stored as directed.

Expiry date

Do not use later than the date of expiry.

Keep medicines out of the reach of children.

Presentation

Bottle of 3 g solution

Marketing Authorization Holder and Manufacturer

Sanofi-Aventis Deutschland GmbH
D-65929 Frankfurt am Main, Germany

THIS MEDICAMENT

Is a product, which affects your health, and its 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 medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers,
Union of Arab Pharmacists.**