SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Nail Batrafen® A
8 % medicated nail lacquer

Active substance: ciclopirox

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g medicated nail lacquer contains 80 mg ciclopirox.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Medicated nail lacquer for application to the nails.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fungal infections of the nails.

4.2 Posology and method of administration

Dosage

Nail Batrafen A is applied in a thin layer every other day in the first month, at least twice weekly in the second month and once a week from the third month onwards.

Method of administration

As much as possible of the destroyed nail material should be removed before the start of treatment with Nail Batrafen A, for example with scissors or with commercially available disposable nail files.

Unless directed otherwise, Nail Batrafen A 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 substance.

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 layer of lacquer is removed once a week with alcohol swabs. During this process, as much of the affected nail material as possible should also be removed with disposable nail files.

If the layer of lacquer becomes damaged in the meantime, it is sufficient to paint over the chipped areas again with Nail Batrafen A.

Duration of administration

The duration of application depends on the severity of the infection, but should not exceed a treatment period of 6 months. The pathogens involved in the fungal nail infection are generally killed during this time. The doctor will decide whether it is necessary to continue treatment.

4.3 Contraindications

Nail Batrafen A should not be used in patients with known hypersensitivity to the active substance ciclopirox or to any of the excipients.

The use of Nail Batrafen A in children and during pregnancy and lactation is not indicated because of a lack of clinical experience.

4.4 Special warnings and precautions for use

None.

4.5 Interactions with medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

The use of Nail Batrafen A during pregnancy and lactation is not indicated because of a lack of clinical experience.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The incidences of undesirable effects are based on the following categories:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

General disorders and administration site conditions

Where Nail Batrafen A has come into contact with skin adjacent to the nail, reddening and desquamation have been observed in very rare cases. Rare cases of allergic contact dermatitis have occurred.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the

Bundesinstitut für Arzneimittel und Medizinprodukte
Abt. Pharmakovigilanz
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: www.bfarm.de

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal agents for dermatological use, ATC code: D01AE14.

Study results on the mechanism of action indicate that the fungicidal effect of ciclopirox olamine is based on inhibition of the cellular uptake of vital cell constituents, while at the same time the efflux of other essential cell components is induced.

Ciclopirox olamine accumulates strongly in the interior of the fungal cell, where it is irreversibly bound to certain structures and organelles such as the cell wall, cell membrane, mitochondria, ribosomes and microsomes.

No evidence of metabolisation of ciclopirox olamine by the fungal cell has been found.

Comparative studies have shown that ciclopirox and ciclopirox olamine have the same type of antimicrobial effect for a relevant spectrum of dermatomycosis pathogens.

5.2 Pharmacokinetic properties

Penetration of ciclopirox from the nail lacquer into excised onychomycotic human fingernails
Release of the radiolabelled active substance (^{14}C) from the nail lacquer and penetration into excised onychomycotic nails produces tissue concentrations in the deeper nail layers equivalent to 2 to 10 times the minimum inhibitory concentration for relevant pathogens in onychomycoses within 24-48 hours.

In vivo studies on the penetration of ciclopirox from the nail lacquer into healthy human fingernails
As the conditions in excised nails provide only a very limited reflection of the in vivo situation, penetration of ciclopirox from the lacquer into the nail plate of healthy fingernails was studied. The presence of the active substance was detected by means of a biotest (inhibition of the growth of Candida pseudotropicalis). This test revealed sufficient tissue concentrations of ciclopirox in various layers of the nail plate to totally inhibit growth of the test pathogen. The increase in the diffusion gradient to steady state was achieved in 14 days. In addition, distribution of the active substance throughout the entire nail plate was relatively homogeneous, at least in the distal portion. This study showed that the ciclopirox that penetrates the nail plate remains microbiologically active.

No data are available on absorption through the nail plate and systemic uptake of ciclopirox, but this should be well below a value of 1.3 % (dermal absorption).

There is no evidence to suggest that the toxicological data obtained for ciclopirox olamine cannot be extrapolated to the use of ciclopirox.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monobutyl maleate-methyl vinyl ether copolymer (1:1), ethyl acetate, 2-propanol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Bottle containing 1.5 g medicated nail lacquer:	2 years.
Bottle containing 2.5 g, 5 g or 7 g medicated nail lacquer:	3 years.

Once the bottle has been opened, Nail Batrafen A is stable as follows if stored as directed:

Bottle containing 1.5 g medicated nail lacquer:	2 months.
Bottle containing 2.5 g medicated nail lacquer:	4 months.
Bottle containing 5 g or 7 g medicated nail lacquer:	6 months.

6.4 Special precautions for storage

Keep the bottle in the outer carton in order to protect from light.

Bottle containing 1.5 g or 2.5 g medicated nail lacquer: Do not store above 30 °C.

6.5 Nature and contents of container

Glass bottles with screw cap and inserted brush.

Bottle containing 1.5 g medicated nail lacquer
Bottle containing 2.5 g medicated nail lacquer
Bottle containing 5 g medicated nail lacquer
Bottle containing 7 g medicated nail lacquer

6.6 Special precautions for disposal and other handling

To prevent the solution from drying up, Nail Batrafen A should be tightly sealed after use.

To prevent the screw cap from sticking to the bottle, avoid spilling solution on the screw thread.

7. MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Deutschland GmbH
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Germany

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8. MARKETING AUTHORISATION NUMBER

30225.00.00

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27.07.1993/08.10.2002

10. DATE OF REVISION OF THE TEXT

July 2014

11. LEGAL CATEGORY

Over the Counter (OTC)

* € 0.06 per call (from a German landline); max. € 0.42/min (mobile networks).