

FUNGAL NAIL PEN INFORMATION LEAFLET

The <Fungal Nail Pen> is a medical device for the treatment of fungal nails.

- Treats fungal nails
- Stops the growth of fungi that cause fungal nails already after 1 hour or
Stops the growth of fungus within one week
- Improves appearance of the nail and reduces discoloration of the nail
- Formulation clinically proven effective
- Visible results within 1 week*
- Prevents spread of the infection and helps to prevent re-infection
- Effective for long term and heavy sufferers of fungal nails.
- Improvement of the structure of the nail starts within 2 weeks

Please read this leaflet carefully before you start using this product because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Contact your doctor if your symptoms worsen or do not improve.
- If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Ask your doctor or pharmacist if you need more information or advice.

The <Fungal Nail Pen> contains a colorless liquid in a pen with a twist system. This twist system helps to apply a small amount of solution to the nail and the brush tip of the pen assures quick and easy application. One pen is sufficient for the treatment of 1 nail during 4 months.

The <Fungal Nail Pen> improves the appearance of the nail and reduces discoloration. Clinical research with this formula showed at most users visible results within 2 weeks.*

** In the PMCF survey is described that visible improvement of the nail starts at week 1 (35% of the respondents) and is very well noticeable after 2 weeks (61% of the respondents) upon treatment with <REF 001 tradename>. Study with 73 test persons.*

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How to use

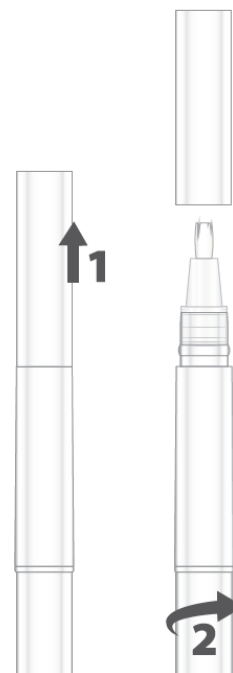
The <Fungal Nail Pen> is indicated for adults. There is limited experience in children. Therefore, consult your doctor before treatment in children.

To prevent spreading of the infection the pen should be used by one person only and on fungal nails only.

Apply the solution once daily to clean and dry nail(s), preferably in the evening just before bed time:

1. Remove the cap.
2. Rotate slowly the end of the pen until the brush is damp. At first use this can take a while.
3. Apply a thin layer on the affected nail(s); Do not apply on the surrounding skin, this can cause skin irritation. Place the cap back on the pen.
4. Allow the nail to dry for a few minutes.

The best results are seen by daily treatment as long as the nail is affected. Duration of treatment varies according to the severity of the condition, and should be continued until a healthy nail has grown out. In most cases a new nail will grow within 6-12 months. If, after 3 months treatment, not any result is observed, consult a physician to discuss alternative or additional treatment.



The solution acts only locally and can therefore be used during pregnancy and lactation.

When should you not use this product?

If you are allergic to any of the ingredients.

Possible Side Effects

In some patients, transient minor irritation of the skin immediately adjacent to the nail and discoloration of the nail may occur. In addition, loosening/separation of the nail from the underlying nail bed may occur, including detachment of the affected part of the nail.

Shelf Life and Storage

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SGQ n° 50 100 7070
SGQ n° Q5 063353 0009
MDSAP n° QS6 063353 0010



EN ISO 22716:2007
CERTIFICATO n° 50 100 14862/COS



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To prevent the use of deteriorated product and lack of effect:

- Always place the cap tightly on the pen after use to prevent dehydration
- Do not use after the expiry date shown on the pen and on the carton.
- Do not use longer than 6 months after opening.
- Store at room temperature, 25°C. Don't keep in fridge or freezer.

Disposal

- Do not throw away the <Fungal Nail Pen> via wastewater or household waste. Ask your pharmacist how to throw away <Fungal Nail Pen> you no longer use. These measures will help protect the environment.
- Do not use the product if the product is not stored as specified above. If the product has been stored temporarily above 25°C (no longer than 1 month up to 40°C) then the product can be safely used.

Warnings

- For external use on the nail only.
- Avoid contact with skin, eyes or mucous membranes as irritation may occur.
- Apply carefully to the nail only, to avoid possible irritation of surrounding normal skin.
- In case of swallowing the product or in case of allergic reactions consult a physician.
- Keep out of the reach and sight of children to prevent risk of choking on cap.

If you experience a serious incident, which leads to for example hospitalization, linked to <REF 001 tradename> please notify the manufacturer and the local authorities.

Content: 4 ml

Ingredients: Monopropylene Glycol 50%, Water, Lactic Acid 15%, Urea 10%, Sodium Hydroxide



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Include full address of entity responsible for translation

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Include full address of the distributor



Explanation of the symbols in the instructions for use, carton box and label.



Use-by date



Medical device



Batch code



Caution



Consult instruction for use



Single patient multiple use



Unique device identifier



Country of manufacture



Manufacturer



Catalogue number



Distributor



Translation

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