

IE Instructions for use



Carefully consult the instructions for use before using Mycosan Fungal Nail treatment kit, even if you have used this product before. The information may have been amended according to new research and findings since you last used the product. Store the instructions for use for future reference.

MYCOSAN



Clinically Proven treatment kit for fungal nails

Suitable for diabetics and children of 4 years and older.



SUITABLE FOR
DIABETICS

Mycosan Fungal Nail treatment kit is available in:

5 ml kit – for the treatment of one affected nail / 10 ml kit – for the treatment of multiple affected nails

Indications for use

Mycosan Fungal Nail treatment kit treats fungal infections on the nail (*white superficial onychomycosis (WSO)* & *distal lateral subungual onychomycosis (DLSO)*) caused by fungi such as *T. rubrum*, *T. mentagrophytes* and *E. floccosum*.

Onychomycosis is a fungal infection of the nails that causes discoloration, thickening, and separation from the nail bed. A fungal nail needs to be treated to prevent the fungal infection from spreading or worsening.

Intended Purpose

Mycosan Fungal Nail treatment kit is intended to form a film on the nail that inhibits the growth of the fungi, involved in fungal infection, with the support of acidification.

Why use Mycosan Fungal Nail treatment kit?

- ✓ **Mycosan serum:** proven effective against fungi, it stops the development of fungi causing fungal nails
- ✓ **Precision Brush:** for the exact dosage on hard-to-reach areas
- ✓ **10 nail files:** for better efficacy. Due to filing, the serum penetrates the nail better
- ✓ **Suitable:** for diabetics and children of 4 years+

Content Mycosan Fungal Nail treatment kit:



1) PRECISION BRUSH:

Targeted application of the Mycosan serum on difficult to reach areas.



2) 10 x NAIL FILE:

For better and optimal result.



3) TREATMENT SCHEDULE:

Supporting an effective treatment.

Mycosan Fungal Nail serum has a 3-fold effect:

1. Effective

Its targeted action rapidly stops the development of the fungi that causes the fungal nail.

2. Restores the nail

It penetrates the nail and improves its structure so that the natural state of the nail is repaired.

3. Improves the appearance of the nail

It helps against discoloration of the nail

Ingredients

Aqua, rye ferment filtrate, pentylene glycol, dimethyl isosorbide (1.5%), hydroxyethylcellulose (0.7%).

Use

Before use, clean and dry nails and where appropriate, remove all traces of nail polish.

File the nail, apply Mycosan Fungal Nail treatment and let it dry. **[FIG.01]**

FIG. 01

Step-by-step process for using Mycosan Fungal Nail treatment



1. File



2. Apply



3. Dry

What is nail fungus?

Nail fungus or onychomycosis is a fungal nail infection occurring in the nail and causing its gradual destruction. It is characterized by the changing appearance of the nail, with the nail plate becoming thickened and yellow in colour and beginning to separate from the nail bed. Pain, especially during walking, may be experienced. Without treatment, the condition is likely to become worse and the infection may spread to other nails, the skin, or even contaminate other individuals.

What can cause nail fungus?

Many factors promote the appearance of nail fungus: micro-traumas, wearing synthetic socks, narrow shoes, certain sports including swimming, hiking or marathon running and, generally speaking, all situations in which feet are prone to sweating, maceration, dampness and repeated shock. Nail fungus results from fungal contamination of the nail after prior infection of the skin, as for example in athlete's foot. In fact, when poorly treated or left entirely untreated, skin fungal infections can spread and cause nail fungus. It should be noted that certain individuals are more easily subject to fungal nail infection: diabetics, people suffering from blood circulation problems, and those with occupations requiring the wearing of safety shoes or boots, etc. If the problem persists, consult your doctor or pharmacist.

How can you treat it?

When a nail is damaged by fungus, its repair process takes a long time in most cases. A toenail may take up to 6 or even 9 months to outgrow completely! It is therefore important to take action as soon as the nail begins to show the first signs of deterioration, and to continue use of Mycosan Nail as directed in this leaflet for successful treatment.

Treatment of nail fungus consists first in inhibiting its development in the affected nail, and later in ensuring the growth of a healthy nail. At the same time, it is important to reduce all risk of contamination to surrounding nails.

Active treatment: finish the treatment for a successful result!

Apply a small drop of serum twice a day for four weeks on the affected nail. A small drop is sufficient. Leave on to dry for one minute. After four weeks apply Mycosan Nail serum once a day until the affected area has grown out.

ATTENTION! Squeeze the tube gently.

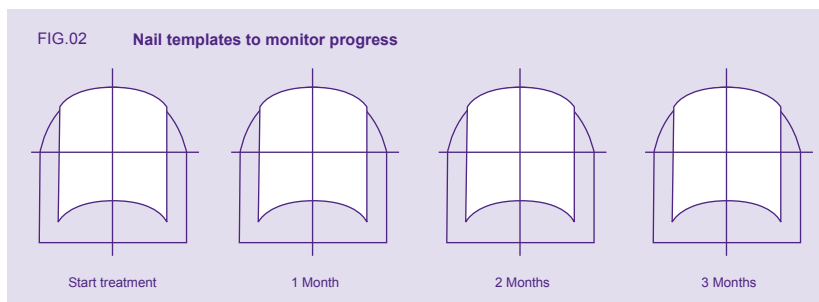
Filing is important!

After treating the nail for one week, carefully file down excessive thickness of the affected area with accompanying nail files once a week. By filing the nail the serum will penetrate the nail plate easier for optimal results.

ATTENTION! Use every nail file only once to prevent spread of infection

Nail template to monitor progress

In order to monitor the progress of the nail, make a pencil note of the area affected by the fungus every month on the diagram below. This will help you measure the progress made. [FIG. 02 - nail template]



Mycosan Fungal Nail treatment schedule

- For a successful treatment, it is important to follow the treatment schedule consistently.
- Use the schedule below to keep track of your improvement.
- Even though improvement may not be so visible in the first month, this does not mean that the treatment is not working. Human nails grow slowly and it may take 6 to 9 months before the affected area is completely grown out. Treat the nail consistently and monitor your progress with the nail template.

[FIG. 03 - treatment schedule]

FIG. 03 Start date treatment: _____

Week	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	File
1	1 2	1 2	1 2	1 2	1 2	1 2	1 2	0
2	1 2	1 2	1 2	1 2	1 2	1 2	1 2	1
3	1 2	1 2	1 2	1 2	1 2	1 2	1 2	1
4	1 2	1 2	1 2	1 2	1 2	1 2	1 2	1
5	1	1	1	1	1	1	1	1
6	1	1	1	1	1	1	1	1
7	1	1	1	1	1	1	1	1
8	1	1	1	1	1	1	1	1
9	1	1	1	1	1	1	1	1
10	1	1	1	1	1	1	1	1
...								1

NB. Cross (x) the schedule every time you have treated or filed your nail

Possible side effects

Immediately stop treatment if you see signs of irritation or outbreak. If the problem persists, consult your health care professional.

If a serious incident has occurred in relation to the product, report to the manufacturer mentioned on the leaflet and the competent authority in your country.

Precautions for use

- For external use on toe- and fingernails only.
- When pregnant or breastfeeding, only use Mycosan Fungal nail if instructed by and under supervision of a health care professional.
- Store out of reach of children.
- Mycosan Fungal Nail must not be used in cases of known hypersensitivity to one of the ingredients.
- Mycosan Fungal Nail is for personal use only to prevent infection of others.
- Squeeze the tube gently and close the cap securely after use.

Recommendations to optimise the efficacy of Mycosan Fungal Nail treatment kit

- Dry your hands and feet securely after washing, also between fingers and toes.
- Cut nails short and avoid biting. Nail biting makes the nails more vulnerable to fungi.
- Opt for wearing absorbent socks to keep your feet fresh and dry. Change them regularly in case of high perspiration.
- Change shoes regularly and let them air out and dry well in between. Avoid wearing shoes made from synthetic materials.
- Choose well-fitting shoes that are not too narrow or too tight, allowing your feet to breathe.
- Always wear slippers in high-risk public places (changing rooms, pools, saunas etc.).
- Treat a fungal infection of the skin (e.g. athlete's foot) with an antifungal cream. With this type of infection, it is also recommended to treat socks and shoes with an antifungal powder and to use a separate towel.

FOR MORE INFORMATION, PLEASE VISIT WWW.MYCOSAN.COM



Shelf life and storage

Do not refrigerate or freeze.
Store out of reach of children.



Keep tube away from sunlight



Lot number and expiration date:
see box & tube

When the treatment is complete dispose of the tube, leaflet and carton as with any common urban waste.



Manufacturer

Serrix B.V.
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Distributor

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Single patient, multiple use



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Medical Device