

# Excilor® ULTRA Colour



Excilor® ULTRA Colour  
to treat the infected  
nail(s).



Cosmetic Nail Laquer  
to cover the healthy  
nails.

## When should you use Excilor® ULTRA Colour?

For the treatment of fungal toe nail infection (onychomycosis) in adults.

- Treats and covers
- Extra strong against nail fungus
- Coloured treatment + Coloured regular nail polish
- Clinically Proven
- 24 h slow-release penetration

**Read the leaflet carefully before treatment.**

## What is onychomycosis?

Onychomycosis is a fungal nail infection that is caused by dermatophytes. The infection usually starts at the rim of the nail and turns the nail whitish-yellow, brown or green. The fungus grows under or into the nail and causes the nail plate to thicken and to break off. Sometimes the distorted nail becomes partially or completely detached, which may be painful.

## How do you get fungal nail infection?

A fungal nail infection is often caused by excessive moisture, heat, perspiration, ageing or a weakened immune system. Normally, the nail plate is too thick for fungi to penetrate. However, damaged nails can easily become infected. Shoes that are too tight and/or feet that perspire provide conditions for fungi to develop and spread. Fungal infections are contagious and can be passed on to others (e.g. by using communal showers). Self-contamination is also possible: the infection can spread from one nail to another. Some people (diabetics, patients on corticosteroids, patients with compromised immune systems) are more prone to fungal infections. Therefore, it is important to treat fungal nail infections as soon as possible: the smaller the infected area, the shorter the period of treatment. Early treatment can also prevent the infection from spreading to other nails.

## How do you prevent fungal nail infection?

Wash your feet regularly. If soap is used, rinse your feet thoroughly afterwards to remove all traces of the soap.

Dry your feet thoroughly, especially between the toes.

Wear clean cotton or woollen socks.

Wear shoes that allow your feet to “breathe” and are not too tight.

Change your shoes regularly.

Use an antifungal product in your shoes.

Wear sandals in areas where a lot of people walk barefoot, for example in communal showers, changing rooms and swimming pools.

## Instructions for use

**1. Excilor® ULTRA Colour** must be applied once a day preferably after showering. Before application clean the nail and remove any old layers of nail varnish. **Shake the bottle well before application.**

**2.** Next, apply a uniform coating of **Excilor® ULTRA Colour** on the whole nail surface to treat. Gently remove any excess of product from the borders of surrounding skin. The bottle may contain clots of dried film residue. Wipe off any clots of dried film from the brush. This is normal and caused by drying from air contact. It has no influence on product performance or quality.

**3.** Allow the nail to dry. This takes between **3 to 5 minutes**. A slightly glossy film is formed. For optimal effect it is advisable to wait for up to 5 minutes before putting on socks and/or shoes. After application, a tingling sensation under the nail is normal and indicates that the product is penetrating the nail. **Excilor® ULTRA Colour** should not be used on healthy nails. A normal nail lacquer with the same colour is available in the box.

**4.** The formed coating is water-resistant and withstands normal wear and friction. The coating may chip off at the edges of the nail but this does not affect product efficacy.

**5. After 24h, remove the film.** You can do this by peeling off the coating at the edge or side of the nail. **Gently roll off until the complete coating is released from the nail.** You may find this easier by using warm water. Apply new product, as instructed above. Wash your hands well after each removal and subsequent application.

For best results, treat the complete nail for a minimum of three months and continue the course of treatment until the nail has recovered completely.

Make sure that the bottle is fully closed after each treatment to prevent evaporation. At the boarder of the glass film formation may occur.

## How does Excilor® ULTRA Colour work?

The most important constituent of toe and finger nails is keratin; a hard and dense substance that most anti-fungal preparations cannot penetrate. In most cases fungi grow underneath the nail and that makes it difficult to treat.

**Excilor® ULTRA Colour** controls the micro-environment of the nail by acidifying the nail bed. **Excilor® ULTRA Colour contains acidic substances** that are able to penetrate the nail and permit treatment from the inside out. It usually takes a few months before an affected nail looks completely healthy again. On average, a toenail grows 1.5 mm in one month. **Excilor® ULTRA Colour** immediately lowers the pH of the nail, creating an environment that is hostile to fungal growth. However, the damaged nail needs time to grow out. The efficacy of the treatment is proven in clinical trials.



## Precautions

For external use only.

Apply on nail only, avoid contact with the surrounding skin.

Avoid all contact with eyes and mucous membranes. If the product comes into contact with eyes or mucous membranes, rinse thoroughly with water.

No clinical data are available on use of the product on children, pregnant or breastfeeding women.

Diabetics with foot problems should consult their doctor when starting to use **Excilor® ULTRA Colour**.

It is best to continue the course of treatment until the nail has recovered completely.

If no effects are observed after 3 months of treatment, consult your GP.

## Possible side effects

Burning sensation, itching or mild, localized pain.

If symptoms persist or worsen, stop treatment and consult your pharmacist or doctor.

Please report suspected serious incidents with this product to **info@excilor.com.au**, as this is important for the continued monitoring of the benefit/risk balance of the product.

## Contra-indications

Do not use if you have a known hypersensitivity or allergy to any of the ingredients.

## Composition Excilor® ULTRA Colour NUDE

Polyurethane-32, Aqua, Acetic acid (3.00% w/w), Iodopropynyl Butylcarbamate, Sorbitan Sesquioleate, Polysorbate 80, Cetyl Acetate, Acetylated Lanolin Alcohol, Dehydroacetic Acid, Benzyl Alcohol, Phenethyl Alcohol, Ethylhexylglycerin, Tocopherol, 1,2-Hexanediol, Caprylyl Glycol, Biotin, Xanthan gum, C12-13 Alkyl Lactate, Pinus Sylvestris Oil, CI 77891, CI 11680, CI 12490, CI 74160, Sodium Citrate, Sodium Laureth Sulfate, Diethylhexyl Sodium Sulfosuccinate, Glycerin.

## Composition Excilor® ULTRA Colour RED

Polyurethane-32, Aqua, Acetic acid (3.00% w/w), Iodopropynyl Butylcarbamate, Sorbitan Sesquioleate, Polysorbate 80, Cetyl Acetate, Acetylated Lanolin Alcohol, Dehydroacetic Acid, Benzyl Alcohol, Phenethyl Alcohol, Ethylhexylglycerin, Tocopherol, 1,2-Hexanediol, Caprylyl Glycol, Biotin, Xanthan gum, C12-13 Alkyl Lactate, Pinus Sylvestris Oil, CI 11680, CI 12490, Sodium Laureth Sulfate, Diethylhexyl Sodium Sulfosuccinate, Glycerin.

No parabens.

## Storage conditions

Keep out of the reach of children.

Store at room temperature (5-25°C) and keep away from heat or direct sunlight.

Keep the bottle tightly closed.

Shake the bottle well before application.

Do not use the product after the expiry date mentioned on the package.

## Packaging of the medical device

The following pack sizes are available:

**Excilor® ULTRA Colour** - 30 ml bottle

VE10553

## Packaging of the Cosmetic Nail Lacquer

### Composition Cosmetic nail lacquer NUDE

INGREDIENTS: Butyl Acetate, Ethyl Acetate, Nitrocellulose, Adipic Acid/Neopentyl Glycol/Trimellitic Anhydride Copolymer, Acetyl Tributyl Citrate, Isopropyl Alcohol, Acrylates Copolymer, Stearalkonium Bentonite, n-Butyl Alcohol, Styrene/Acrylates Copolymer, CI 77891, Silica, Benzophenone-1, Trimethylpentanediyl Dibenzoate, Polyvinyl Butyral, CI 19140, CI 77491, Diacetone Alcohol.

### Composition Cosmetic nail lacquer RED

INGREDIENTS: Butyl Acetate, Ethyl Acetate, Nitrocellulose, Acetyl Tributyl Citrate, Adipic Acid/Neopentyl Glycol/Trimellitic Anhydride Copolymer, Isopropyl Alcohol, Acrylates Copolymer, Stearalkonium Bentonite, n-Butyl Alcohol, Styrene/Acrylates Copolymer, CI 19140, CI 77491, CI 15850, Silica, Benzophenone-1, CI 77891, Trimethylpentanediyl Dibenzoate, Polyvinyl Butyral, Diacetone Alcohol.

8 ml e

Medi-fill BV - Egelskoog 9 - NL 1822 BM, Alkmaar



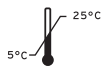
Medical device



Instructions for use



Caution



Temperature limit



Expiry date



Batch code



Keep away from sunlight



Distributor



Manufacturer

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Oystershell NV  
Nijverheidsweg 10  
9820 MERELBEKE  
BELGIUM