



Se till att flaskan är helt stängd efter varje behandling för att förhindra avdunstning. En film kan bildas vid glasets kant.

**Excilor® FORTE** finns i en flaska med 30 ml lösning.

#### Biverkningar

Brännande känsla, klåda eller mild lokal smärta.

Om symtomen kvarstår eller förvärras ska du avsluta behandlingen och kontakta apotekspersonal eller läkare.

Rapportera misstänkta allvariga biverkningar av denna produkt till tillverkaren (Oystershell NV) och den myndighet (Fimea) som har tillsynsansvar över medicintekniska produkter, eftersom detta är viktigt för den fortsatta övervakningen av produktens nytta-riskförhållande.

#### Försiktighetsåtgärder

Endast för utvärtes bruk.

Använd inte om du vet att du är överkänslig eller allergisk mot någon av ingredienserna.

Applicera endast på nageln, undvik kontakt med omgivande hud.

Undvik all kontakt med ögon och slemhinnor. Skölj med mycket vatten om produkten kommer i kontakt med ögon eller slemhinnor.

Inga kliniska data finns tillgängliga om användning av produkten på barn eller hos gravida eller ammande kvinnor.

Diabetiker med fotproblem bör rådfråga sin läkare innan de börjar använda **Excilor® FORTE**.

Använd inte produkten efter dess utgångsdatum.

#### Förvaring

Förvara i förpackningen vid rumstemperatur (5–25 °C) och utsätt den inte för värme eller direkt solljus.

Förvaras utom syn- och räckhåll för barn och djur.

Håll flaskan ordentligt stängd.

Skaka flaskan ordentligt före användning.

#### Ingredienser

Vatten, polyuretan, pepparmyntolja, ättiksyra, sorbitanseskvioleat, hexandiol, oktandiol, bensylalkohol, oktylgallat, etoxilerad och acetylerad lanolinalkohol, fenyletanol, jodpropynylbutylkarbammat, xantangummi, dehydroättiksyra, etylhexylglycerin, biotin.

Patentansökt



Senaste ändring av denna bruksanvisning: November 2020

EN

## Excilor® FORTE

### For the treatment of fungal toe nail infection (onychomycosis)

#### 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.

## Excilor® FORTE

### How does Excilor® FORTE treat fungal nail infection?

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® FORTE** controls the micro-environment of the nail by acidifying the nail bed. **Excilor® FORTE** 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® FORTE** 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 **Excilor® FORTE** is proven in clinical trials.

#### Instructions for use



**Excilor® FORTE** 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 use.



Next, use the brush to coat the whole of the surface of the nail. Make sure to apply a sufficient layer of **Excilor® FORTE**. 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.



Allow the nail to dry. This takes between **3 to 5 minutes**. The product is white when applied but as it dries it **becomes transparent** and you will notice a rubber coating which will decrease with time. 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.



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. The film layer is compatible with nail varnish and when dried nail varnish can be applied.



**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 border of the glass film formation may occur.

**Excilor® FORTE** is available in a bottle of 30 ml solution.

#### 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 the manufacturer (Oystershell NV) and the competent health authority of your country, as this is important for the continued monitoring of the benefit/risk balance of the product.

#### Precautions

For external use only.

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

Apply on nail only, avoid contact with 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 by children, or by pregnant or breastfeeding women.

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

Do not use the product after its expiry date.

#### Storage conditions

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

Keep out of the sight and reach of children and animals.

Keep the bottle tightly closed.

Shake bottle well before use.

#### Ingredients

Water, polyurethane, peppermint oil, acetic acid, Sorbitan sesquioleate, hexanediol, octanediol, benzyl alcohol, octyl gallate, ethox and acet. lanolin alc., phenethyl ethanol, iodopropynyl butylcarbamate, Xanthan gum, dehydro acetic acid, ethylhexyl-glycerine, biotin.

Patent pending



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