

PRACTICE GUIDANCE: OTC AMOROLFINE NAIL LACQUER

Following reclassification from prescription-only to pharmacy medicine status amorolfine 5% nail lacquer is now available for sale over-the-counter (OTC) from registered pharmacies. This guidance outlines the OTC indications for the drug, as well as important points to consider when counter prescribing



Royal
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OTC INDICATIONS

Amorolfine 5% nail lacquer is indicated for treatment of mild cases of fungal infection beneath the tips and sides of nails caused by dermatophytes, yeasts and moulds and affecting up to two nails.

FUNGAL NAIL INFECTION

(ONYCHOMYCOSIS, TINEA UNGUIUM)

Onychomycosis is an infection of the nail apparatus by fungi including dermatophytes, yeasts and moulds. The dermatophyte *Trichophyton rubrum* is the commonest cause of subungual onychomycoses. Dermatophytes also cause skin infections such as athlete's foot (tinea pedis) and ringworm (tinea corporis). Yeasts, such as *Candida*, and moulds are less common causes of onychomycoses.

Both toenails and fingernails can be affected but infection of the toenails is more common. Fungal nail infection is more common where there has been nail trauma, in immuno-compromised patients or in people with diabetes or psoriasis. It is also associated with increasing age, smoking and with the presence of athlete's foot.

Distal and lateral subungual onychomycosis starts at the hyponychium (just under the nail where the nail joins the nail bed). Early infection involves the nail bed and the underside of the nail plate (the hard part of the nail). As the infection spreads the whole of the nail bed becomes involved and the full thickness of nail plate is affected. The nail becomes thickened, discoloured and crumbly or flaky and may separate from the nail bed (onycholysis).

There are two other types of fungal nail infection – white superficial onychomycosis, in which the superficial layers of the nail plate are infected, and proximal subungual onychomycosis, in which the matrix at the base of the nail is affected. Neither of these conditions can be treated with OTC amorolfine nail lacquer.

Dermatophyte onychomycosis progresses relentlessly. Left untreated, it does not go away on its own. Thickened and distorted nails can be a cause of considerable discomfort and embarrassment and can pose special problems for patients with diabetes or peripheral vascular disease.

Several other conditions can cause nail changes that could resemble fungal nail infection. These include psoriasis affecting the nails, nail trauma, eczema, lichen planus, yellow nail syndrome and tumour of the nail bed. Typically these conditions are associated with other changes to the skin or nails that can help to distinguish them from fungal nail infection.

Ideally, suspected onychomycosis should be confirmed by microscopy (to identify the presence of fungal elements) and culture (to identify the species and confirm that it is a pathogen rather than a commensal). Both nail clippings and debris from beneath the affected nail are required. However, given that the treatment is unlikely to do any harm, dermatologists agree that OTC treatment can be started without a positive diagnosis.

HOW DOES AMOROLFINE WORK?

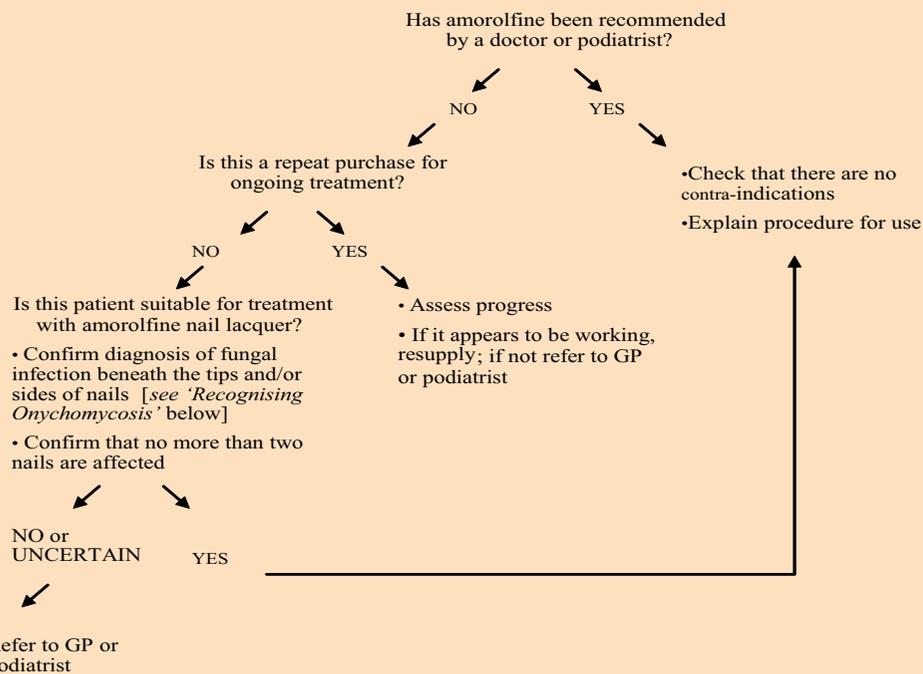
Amorolfine is a topical antimycotic (antifungal) agent that has a fungicidal effect. It inhibits sterol biosynthesis and thereby disrupts the fungal cell membrane leading to cell death. Amorolfine is a broad spectrum antimycotic with activity against a wide range of organisms including dermatophytes (*Trichophyton*, *Micosporum* and *Epidermophyton* species), yeasts (*Candida*, *Cryptococcus* and *Malassezia* species) and moulds.

When the amorolfine nail lacquer is applied to the nail surface the solvent evaporates to leave a highly concentrated deposit of amorolfine in an occlusive film on the nail. This acts as depot from which amorolfine penetrates and diffuses through the nail plate over the next seven days. In this way, amorolfine is delivered to the nail bed.

PRACTICE POINTS

- In order to be effective this treatment must be applied regularly (weekly) for up to 12 months. the clinical trial situation and the effects of these on drug treatment are unknown.
- Patients should not expect to see much difference in the first three months – this is a long-term treatment.
- Failure to complete the treatment or follow the instructions correctly can result in a recurrence of symptoms.
- Remembering to use the treatment can be the most difficult part; applying amorolfine on the same day each week and writing the date of use on a diary card or on the box helps to keep a running check.
- Remind patients to avoid allowing the lacquer to come into contact with eyes, ears and mucous membranes.
- People with underlying conditions that predispose to fungal infections, such as peripheral circulatory disorders, diabetes mellitus and immunosuppression, should be referred to their GP.
- People with nail dystrophy and destroyed nail plates should be referred to their GP.
- The summary of product characteristics (SPC) for amorolfine nail lacquer advises against the use of nail polish and artificial nails because this mirrors the clinical trial situation and the effects of these on drug treatment are unknown.
- Occasionally patients have a slight, transient, burning sensation in the areas of the nails after the application of the lacquer. It is safe to continue to use the product.
- If the fingernails are affected, patients should be advised to wear impermeable gloves when working with organic solvents (thinners, white spirit, etc.) in order to avoid inadvertent removal of the lacquer from the nails.
- The amorolfine nail lacquer pack is designed to last for three months. Review progress with patients before supplying the next pack. Encourage patients to use the diagram templates in the pack to chart progress at three-monthly intervals.
- Debris from infected nails can be a source of reinfection for skin. Keep skin cool and dry as far as possible and use a topical fungicidal treatment such as terbinafine at the first sign of infection.
- Damaged nails are more likely to become infected than healthy, intact nails.
- Never use the same nail file for infected and healthy nails as infection could be transferred in this way. Use disposable nail files for infected nails.

WHO IS ELIGIBLE FOR OTC AMOROLFINE NAIL LACQUER?



RECOGNISING ONYCHOMYCOSIS

Are the following features present?

- the nail is thickened and has turned yellow/ white at the tip
- the changes appear to have spread along the length of the nail towards the nail base
- debris has accumulated under the nail; scaling and distortion of the nail has occurred

In addition, the nail may have become brittle and some or all of it may have broken off.



Distal and lateral onychomycosis - suitable for treatment with amorolfine nail lacquer



White superficial onychomycosis - should be referred for treatment



Proximal onychomycosis - should be referred for treatment

Photos: Galderma (UK) Ltd

Amorolfine has to be applied regularly until all of the affected nail tissue has grown out. This takes nine to 12 months for toenails and six months for fingernails.

HOW TO USE AMOROLFINE NAIL LACQUER

The nail lacquer should be applied to the affected fingernails or toenails once weekly.

Before the lacquer is applied, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as far as is comfortable using one of the disposable nail files supplied. The surface of the nail should then be cleansed and degreased using one of the disposable cleaning pads.

The disposable nail files used for affected nails should be discarded after use and must not be used for healthy nails, as fungal spores could be transferred in this way.

Patients should be advised to apply the nail lacquer using one of the reusable applicators supplied. For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the neck of the bottle. Touch the nail with the end of the applicator and the lacquer will flow over the nail surface. Allow the lacquer to dry.

After use, clean the applicator with the cleaning pad used earlier for nail cleaning. Keep the bottle tightly closed.

Before repeat applications of the lacquer, residual lacquer should be removed (using the pads) and the affected nails should be filed down again as required.

Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured.

CO-EXISTENT ATHLETE'S FOOT

Co-existent athlete's foot should be treated with an appropriate antimycotic cream. For preference, a

fungicidal agent, such as terbinafine, rather than a fungistatic agent should be recommended.

CONTRA-INDICATIONS

Amorolfine nail lacquer must not be used by patients who have shown hypersensitivity to the treatment in the past.

Amorolfine nail lacquer should be avoided during pregnancy and breast-feeding. There is no experience of the use of this product during pregnancy and breast-feeding although the systemic absorption of amorolfine during and after topical administration is very low and therefore the risk to the foetus appears to be negligible.

Amorolfine nail lacquer is not recommended for patients under the age of 18 years.

CAUTIONS

Avoid allowing the lacquer to come into contact with eyes, ears and mucous membranes.

People with underlying conditions that predispose to fungal infections, such as peripheral circulatory disorders, diabetes mellitus and immunosuppression, should be referred to their GP.

People with nail dystrophy and destroyed nail plates should be referred to their GP.

ADVERSE EFFECTS

Occasionally patients experience a slight, transient, burning sensation in the areas of the nails after the application of the lacquer.

DRUG INTERACTIONS

There are no specific studies of concomitant treatment with other topical medicines and the systemic absorption of amorolfine is very low. The SPC advises against the use of nail polish and artificial nails during treatment.