

PSI guidance on non-prescription Curanail (Amorolfine) Medicated Nail Lacquer

May 2012

The Irish Medicines Board recently granted a marketing authorization for Curanail Medicated Nail Lacquer containing 5% w/v of Amorolfine, as a non-prescription medicinal product for the treatment of mild cases of fungal nail infections¹ for use in adults, and only if up to two nails are affected.

It is expected that the product will become available to pharmacies in early June 2012.

The PSI wishes to advise pharmacists of its guidance in respect to the sale and supply of Curanail :

- The supply of Curanail, and the associated assessment and consultation with a patient, should only be carried out by a pharmacist.
- Patients seeking treatment for this condition, or requesting this particular product, should therefore be referred to the pharmacist for a consultation.
- This consultation and discussion should take place in the pharmacy's patient consultation area.
- Each time this medicine is supplied, the pharmacist must be satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is safe and appropriate for the individual patient.
- With respect to the supply of this medicine to a person, other than the person for whom it is intended to treat, the pharmacist must be satisfied that the supply is appropriate and in the best interest of the patient. At a minimum, as required under Regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008, the pharmacist should be satisfied that the purchaser is aware of the appropriate use of the product. The person for whom the product is intended should be encouraged to attend at the pharmacy for an assessment of their condition.
- Pharmacists should be familiar with the product SmPC and patient information/package leaflet in order to satisfy themselves that the patient's condition meets the product indications and that there are no contra-indications or cautions regarding use of this product for the individual patient. Patients will seek the pharmacist's advice in relation to their particular symptoms or condition, so familiarity with the diagnostic criteria is important.
- As this is a relatively long-term treatment, pharmacists should give consideration to being able to track the duration of treatment, particularly for individuals who are regular patients and who will return to the pharmacy for assessment as to whether they are getting benefit from the treatment or seeking a further supply, and who may in some cases expect the pharmacist to assist them keep track of the duration and progress of treatment.

¹ In the Summary of Product Characteristics, these infections are described as mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds.

- If any records are being kept of the supply of Curanail, where this is deemed appropriate in the patient's interests and the pharmacist's professional judgement, this recording should be made with the patient's full knowledge and consent, and patients must be assured of the confidentiality of such records. The management of any data or information recorded, collected or retained should be in accordance with relevant legislative provisions, including those of the Data Protection Acts 1988 and 2003.
- Due to the requirement for the pharmacist to personally carry out the supply, Curanail should be stored/located within the pharmacy under the direct supervision and control of the pharmacist.
- As with all medicines, any suspected adverse reaction should be reported to the Irish Medicines Board, preferably online, via the IMB website www.imb.ie.

Note: Pharmacists should be aware the Irish SmPC for Curanail states that *"Amorolfine is not expected to have any effects during pregnancy and lactation as systemic exposure is negligible. Amorolfine can be used during pregnancy and lactation."* This differs from the current UK SmPC which states that the use of this product should be avoided during pregnancy and breastfeeding.