CURANAIL 5% NAIL LACQUER (AMOROLFINE HYDROCHLORIDE)
PL 10590/0049

UKPAR

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LAY SUMMARY

The MHRA granted Galderma (UK) Limited a Marketing Authorisation (licence) for the medicinal product Curanail 5% nail Lacquer (PL 15909/0049) on 7th April 2006. This medicine which is available from Pharmacies is used to treat mild fungal infections of the nail in up to 2 nails.

Curanail 5% Nail Lacquer contains the active ingredient amorolfine (as the hydrochloride), which is one of a group of medicines known as anti-fungals, which kill a wide variety of fungi which can cause infections.

This new product is a duplicate of a previously granted application for Loceryl Nail Lacquer 5% (PL 10590/0042) held by Galderma (UK) Limited which is available on prescription for more serious fungal nail infections. Curanail 5% Nail Lacquer is for milder fungal infections of the nail and has been granted a different legal supply classification, which means it can be sold in pharmacies.

No new or unexpected safety concerns arose from these applications. It was, therefore, judged that the benefits of Curanail 5% Nail Lacquer being available from a pharmacy outweigh the risks. Hence a Marketing Authorisation has been granted.

CURANAIL 5% NAIL LACQUER
PL 10590/0049

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Curanail 5% Nail Lacquer (PL 10590/0049) to Galderma (UK) Limited on 7th April 2006. The product is available in Pharmacies (P).

The application was submitted according to article 10.c [formerly article 10.1(a)(i)] of Directive 2001/83/EC, cross-referring to Loceryl Nail Lacquer 5% (PL 10590/0042). The cross-reference application was granted on 19th April 1999 as a change of ownership from PL 00031/0285, held by Roche Products Limited which was itself granted a marketing authorisation for on 4th July 1991.

No new quality data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

The product contains the active ingredient amorolfine hydrochloride which is a broad spectrum topical antimycotic agent that has both fungistatic and fungicidal activity against all pathogens of nail mycosis. The product is indicated for the treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails.

PHARMACEUTICAL ASSESSMENT

This abridged simple application is associated with a reclassification application – see medical assessment for the joint medical/ pharmaceutical assessment.

The company has submitted an expert statement confirming that all pharmaceutical aspects are the same as the cross reference product. The Marketing Authorisation Application form has been updated to reflect the current granted licence. The Drug Substance Specification, method of manufacture and Finished Product Specification are consistent with the current granted MA and this is satisfactory

Conclusion

This MA may be approved as a P product.

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