IPAR

Public Assessment Report for a Traditional Herbal Medicinal Product for Human Use

Lamberts Devils Claw Tablets
Harpagophytum procumbens D.C. and / or *H. zeheri* L. Decne
(devil's claw) root extract

TR 2029/3/1

TR Holder: Lamberts Healthcare Limited

I INTRODUCTION

Specific provisions were introduced for traditional herbal medicinal products (THMPs) in accordance with the Traditional Herbal Medicinal Products Directive (2004/24/EC). The national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive came into force on 23rd July 2007. Consequently the HPRA has established the Traditional Herbal Medicinal Products Registration Scheme.

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a Certificate of Traditional Use Registration for a specific traditional herbal medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of EC Directive 2001/83/EC, as amended by Directive 2004/27/EC and Directive 2004/24/EC. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the traditional herbal medicinal product for marketing in Ireland.

Based on the review of the data on quality, safety and traditional use, the HPRA has granted Lamberts Healthcare Limited a Certificate of Traditional Use Registration for Lamberts Devils Claw Tablets, containing a dry extract of devil's claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne, radix).

This application was submitted as a standard application according to Article 16c of Directive 2001/83/EC, as amended, as part of the Traditional Herbal Medicinal Product Registration Scheme.

The Summary of Product Characteristics (SmPC) for this traditional herbal medicinal product is available on the HPRA's website.

II QUALITY ASPECTS

This application is for Lamberts Devil's Claw Tablets. The active ingredient, of Lamberts Devil's Claw Tablets, is obtained from the root of the *Harpagophytum procumbens* D.C. and / or *H. zeheri* L. Decne (devil's claw) root.

II.1 S.1 Herbal Substance

The herbal substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.2 S.2 Herbal preparation

The herbal preparation is devil's claw (root) dry extract, and is manufactured in accordance with the principles of good manufacturing practice (GMP).

The herbal preparation specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

The composition of the medicinal product is stated in sections 2 and 6.1 of the SmPC. A description of the product is included in section 3 of the SmPC.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of GMP at a suitably qualified manufacturing site.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with applicable Ph. Eur. specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for tablets, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site has been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging material complies with EU legislation for use with foodstuffs requirements.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Conclusion on quality

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Lamberts Devils Claw Tablets.

III NON-CLINICAL ASPECTS

Lamberts Devils Claw Tablets is a traditional herbal medicinal product as defined by Article 16a(1) of Directive 2001/83/EC as amended.

The HPRA has been assured that GLP standards were followed in an appropriate manner in the studies conducted.

An expert report on safety has been provided which includes an appropriate review of the available literature.

Overall the information presented demonstrating traditional use is considered to be acceptable and the lack of provision of a complete standard safety package is in line with the EMA 'Guideline on Non-clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorisation (bibliographical and mixed applications) and in Applications for Simplified Registration' (EMEA/HMPC/32116/05).

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

IV CLINICAL ASPECTS

This is a national application submitted by Lamberts Healthcare Limited under Article 16c of Directive 2001/83/EC, as amended.

Lamberts Devils Claw Tablets is a traditional herbal medicinal product used for the relief of minor joint pain in adults over 18 years of age, exclusively based on long-standing use.

IV.1 Clinical Efficacy

There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product is efficacious, the registration is based exclusively upon the longstanding use of Lamberts Devils Claw Tablets as a traditional herbal medicine and not upon data generated from clinical trials.

Article 16c1(c) of Directive 2001/83/EC requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community. With regard to this traditional use data, the requirements of Article 16c1(c) have been met.

The efficacy of this traditional herbal medicinal product is plausible on the basis of long standing use and experience.

The indication proposed for Lamberts Devils Claw Tablets is in line with traditional indications recorded and hence, compatible with the requirements of the Traditional Herbal Medicinal Products Directive 2004/24/EC.

IV.2 Clinical Safety

In accordance with Article 16c1(d) the applicant has provided a bibliographic review of the safety data together with an expert report.

This product should not be used in those under 18 years of age as it is not known if it is safe to do so.

Patients who are allergic to Devil's claw or any of the other ingredients of this product should not use Lamberts Devil's Claw Hard Tablets.

Patients with gastric or duodenal ulcers should not use Devil's Claw preparations.

The recommended dose of this product should not be exceeded.

It is recommended that if symptoms persist, worsen or do not improve after 4 weeks of use of this product, a doctor or pharmacist should be consulted.

Patients who have painful, swollen or red joints or a fever should consult a doctor or pharmacist before using this product.

Patients who have heart problems should talk to their doctor or pharmacist before taking this product.

Patients with gallstones should consult a doctor prior to use of Devil's claw.

Women who are pregnant, breast-feeding or planning to have a baby should not take this product.

Possible side effects of this product include nausea, abdominal pain, diarrhoea, vomiting, headache, dizziness, allergic skin reactions, itch and rash.

Some patients may experience dizziness or drowsiness while taking this product. Those who are affected in this way should not drive or use machines.

In conclusion, this product proves not to be harmful in the specified conditions of use based on the review of safety data, expert report and additional data provided.

IV.3 Pharmacovigilance

It should be noted that in accordance with Article 16g of Directive 2001/83/EC, as amended, the pharmacovigilance requirements described in Articles 101- 108 of Directive 2001/83/EC, as amended, also apply in respect of traditional herbal medicinal products.

V OVERALL CONCLUSIONS

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Lamberts Devils Claw Tablets.

The HPRA, on the basis of the data submitted, considered that Lamberts Devils Claw Tablets demonstrated adequate evidence of traditional use for the approved indication(s) and no new preclinical or clinical safety concerns have been identified.

A certificate of traditional use for Lamberts Devils Claw Tablets is granted.