Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lamberts Devils Claw Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each fim-coated tablet contains 450 mg of dry extract from *Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne radix (devil's claw root).
(Equivalent to 1575 – 2250 mg of Devil's claw root)

Extraction solvent: ethanol 60 % v/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
Small, green oval film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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.

4.2 Posology and method of administration

For oral short-term use only.

For adults and the elderly, take one tablet twice a day (in the morning and in the evening). The safety of Lamberts Devils Claw Tablets in children and adolescents under the age of 18 years has not been established as no data are available.

Do not exceed the stated dose.

Tablets should be swallowed whole with some water or other liquid

If symptoms worsen or do not improve after 4 weeks a doctor or qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Patients with active gastric or duodenal ulcer.
The safety of Lamberts Devils Claw Tablets in children and adolescents under 18 years of age has not been established as no data are available.
Do not use in case of known hypersensitivity to the active substance or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If the symptoms worsen during the use of the medicinal product or if symptoms persist for more than 4 weeks, a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

If articular pain accompanied by swelling of joint, redness or fever are present a doctor should be consulted.

Some animal studies done with high concentrations of Devil's claw have indicated that it may have calcium antagonistic effects similar to the calcium channel blocker Verapmil. Therefore caution should be taken when Devil's claw is administered to patients with cardiac disorders.

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

Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

There is no evidence from limited interaction studies that Devil's claw root extracts will interact with other medicinal products.

4.6 Fertility, pregnancy and lactation

There are no or a limited amount of data from the use of Devil's claw in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Lamberts Devils Claw Tablets is not recommended during pregnancy and in women of childbearing potential not using contraception.

There is insufficient information on the excretion of Devils claw/metabolites in human milk. A risk to newborns/infants cannot be excluded. Lamberts Devils Claw Tablets should not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. In rare cases some patients have experienced dizziness and somnolence while taking Devil's claw. If affected, patients should not drive or use machinery.

4.8 Undesirable effects

Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pain. Central Nervous system disorders: headache, dizziness. Skin disorders: allergic skin reactions (rash and itching) The frequency is not known.

If other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@hpra.ie.

4.9 Overdose

There are no data on human overdose with Devil's claw. Symptomatic and supportive measures should be taken as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Standard in-vitro tests for detection of gene mutation (Ames test) with Devils Claw Root did not demonstrate genotoxic activity.

Tests on reproductive toxicity and on carcinogenicity have not been performed with Devils Claw root.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparation
Maltodextrin
Colloidal anhydrous silica

Tablet Core
Maltodextrin
Microcrystalline cellulose
Sodium croscarmellose
Stearic acid
Colloidal anhydrous silica
Magnesium stearate

Tablet Coating
Hypromellose
Glycerol
Titanium dioxide
Copper Chlorophyllin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original packaging.

6.5 Nature and contents of container

Tablets are packed into an aluminium/PVDC blister strips in the following pack sizes: 30, 60 and 90 tablets and packed into a carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Lamberts Healthcare Limited,
1 Lamberts Road,
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8 REGISTRATION NUMBER(S)

TR2029/003/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 16th March 2018

10 DATE OF REVISION OF THE TEXT