Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Natures Aid Jointeeze Devil's Claw

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 300 mg of extract (as dry extract) from Devil's Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne) (equivalent to 1050 – 1500 mg Devil's Claw root).

Extraction solvent: Ethanol 60% v/v.
Also contains glucose monohydrate 0.8 mg
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet)
Brown circular, biconvex film-coated tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product 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 adults and the elderly: swallow one tablet three times daily after food.
The safety of Jointeeze Devil's Claw Tablets in children or adolescents under 18 years old has not been established as no data are available.
Duration of use:
If symptoms do not improve or worsen after 4 weeks, a doctor or qualified healthcare professional should be consulted.
For oral short-term use only.

4.3 Contraindications

Patients with active gastric or duodenal ulcer.
Patients under 18 years of age.
Hypersensitivity to devil's claw or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor.
Patients with gallstones should consult a doctor prior to use of devil's claw.
If the symptoms worsen during the use of the medicinal product or if symptoms persist for more than 4 weeks, a qualified professional e.g. a doctor or a pharmacist should be consulted.
Patients with rare glucose-galactose malabsorption should not take this medicine.
Do not exceed the stated dose.
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 verapamil. Therefore caution should be taken when devil's claw is administered to patients with cardiac disorders.

4.5 Interaction with other medicinal products and other forms of interactions

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 (see section 5.3). Jointeeze Devil's Claw Tablets is not recommended during pregnancy and in women of childbearing potential not using contraception.
There is insufficient information on the excretion of devil's claw/metabolites in human milk. A risk to newborns/infants cannot be excluded. Jointeeze Devil's 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 symptoms (diarrhoea, nausea, vomiting, abdominal pain) have been reported.
Central Nervous System effects (headache, vertigo) have been reported.
Hypersensitivity reactions (e.g. rash, hives, facial oedema) have been reported.
The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

Reportingof suspected adversereactions
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 the national reporting system:
HPRA Pharmacovigilance
Website: www.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

Not required as per Article 16c (1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.
Devil's Claw quantified extract was negative for mutagenicity in a standard Ames test. Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal extract:
Maltodextrin
Silica, colloidal anhydrous

Tablet core:
Calcium hydrogen phosphate dihydrate
Cellulose, microcrystalline

Croscarmellose sodium
Silica, colloidal hydrated
Magnesium stearate

Coating:
Croscarmellose sodium
Lecithin
Glucose monohydrate
Sodium citrate
Dextrin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in original package.

6.5 Nature and contents of container

Ph. Eur. type III amber glass bottles with polypropylene closure incorporating an induction heat seal liner. Printed outer carton containing Patient Information Leaflet.
Pack sizes: 30, 60, 90 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR0126/318/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th May 2020

10 DATE OF REVISION OF THE TEXT