Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nature's Bounty Devil's Claw Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 427mg of extract (as dry extract) from Devil's Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne, radix) (equivalent to 1493mg – 2133mg of Devil's Claw root).

Extraction solvent: Ethanol 60% v/v.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

HardCapsule (Capsules)

Two piece clear hard capsules with grey/brown fill.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product for the relief of minor joint pain in adults, exclusively based upon long-standing use.

4.2 Posology and method of administration

For oral short-term use only

Adults and older people- Take 1 capsule 2 times daily immediately after food. Swallow the whole capsule with water. Take one capsule in the morning and one in the evening

Maximum dose: 2 capsules per day.

Do not exceed the stated dose

Duration of use:
If symptoms persist, worsen or do not improve after 4 weeks use of Nature's Bounty Devil's Claw Hard Capsules, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

The safety of Nature's Bounty Devils Claw Hard capsules in children and adolescents under 18 years of age has not been established as no data are available

4.3 Contraindications

• Do not use in cases of known hypersensitivity to Devil's claw or any of the excipients listed in section 6.1
• The safety of Nature's Bounty Devil's Claw Hard Capsules in children and adolescents under 18 years of age has not been established as no data are available.
• Patients with active gastric or duodenal ulcer

4.4 Special warnings and precautions for use

• Do not exceed the stated dose
• 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 the use of devil's claw.

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). Nature's Bounty Devil's Claw Hard Capsules 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. Nature's Bounty Devil's Claw hard Capsules should not be used during breast-feeding.

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

§ Nervous system disorders such as headache and dizziness.
§ Gastrointestinal disorders such as diarrhoea, nausea, vomiting and abdominal pain.
§ Skin and subcutaneous tissue disorders such as allergic skin reactions (rash and itching)

The frequency of the listed side effects is not known (cannot be estimated from the available data).

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; E-mail: 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

The active constituents of Devil's claw have not been definitely established. However, the iridoid glycoside constituents, such as harpagoside, are considered to play an important role in its activity. It is thought that Devil's claw root does not produce the biochemical effects on arachidonic acid metabolism characteristic of the NSAIDs used to treat arthritis.

5.2 Pharmacokinetic properties

Non-clinical pharmacokinetic studies have not been conducted.

5.3 Preclinical safety data

Tests on reproductive toxicity and carcinogenicity have not been performed.

An *in vitro* Ames study has shown the quantified dry extract used in Devil's Claw is non-mutagenic

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Hydrogen phosphate dihydrate
Microcrystalline cellulose
Magnesium stearate
Silica colloidal hydrated
Maltodextrin
Silica colloidal anhydrous

Capsule shell:
Hypromellose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC.
Keep the bottle tightly closed in order to protect from light and moisture

6.5 Nature and contents of container

Green polyethylene terephthalate (PET) bottles with a polypropylene cap and an inner seal liner made up of polyester, polymer adhesive layer, polyolefin foam and aluminium foil.

Pack size:
50 capsules
100 capsules
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)

TR23157/010/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 3rd May 2013
Date of last renewal: 2nd May 2018

10 DATE OF REVISION OF THE TEXT

February 2021