Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atrosan Devil's Claw film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 480 mg of extract (as dry extract) from
Harpagophytum procumbens D.C. and/or H. zeyheri L. Decne, radix (Devil's claw root).
(1.5 – 3.0:1).
Extraction solvent: Ethanol 60% v/v.

Excipients with known effect:
Each tablet contains 226.08 mg lactose monohydrate.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet)
It is an oval-shaped, white coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product for the relief of minor articular pain, exclusively based on long-standing use.

This product is indicated for use in adults.

4.2 Posology and method of administration

Posology
Adults and older people: One tablet twice daily immediately after food.

The dose can be increased to two tablets twice daily if relief is not obtained after 3 to 5 days.

This product is not indicated in patients less than 18 years old.

If the condition worsens, new symptoms develop or symptoms persist during the use of Atrosan or for more than four weeks, a doctor should be consulted.

Method of Administration
For oral short-term use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active substance or one of the excipients listed in section 6.1.

Patients under 18 years of age.

Pregnancy and lactation.

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, a qualified health care professional e.g. a doctor or pharmacist should be consulted.

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

The dosing and safety of Devil's claw have not been studied thoroughly in children and adolescents and safety is not established.

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.

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

This product contains lactose. One film-coated tablet contains a maximum of 226.08 mg lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Therefore, Atrosan should not be used during pregnancy and lactation.

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.

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 glucoside 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

Preclinical data reveal no special hazard for humans based on conventional studies of single dose toxicity, repeated dose toxicity and genotoxicity.

Carcinogenicity studies and studies on reproduction have not been conducted, however as there is evidence of oxytocic effects of Devil's claw, its use in pregnancy is contra-indicated.

Two *in vitro* studies have shown this Devil's claw extract to be non-mutagenic in the *Salmonella typhimurium* reverse mutation assay up to the dose of 5,000µg/plate, and non-clastogenic in the *in vitro* chromosome aberration test at concentrations up to 867.5µg/ml.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet:
Lactose monohydrate
Maize starch
Cellulose, microcrystalline
Silica, colloidal anhydrous
Purified water
Magnesium stearate (vegetable source)
Silica, precipitated

Film coating:
Talc
Titanium dioxide
Macrogol
Hypromellose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottles (type III conforming to Ph.Eur. standards) with coated aluminium foil sealing and aluminium pilfer proof screw cap fitted with a polyethylene liner.
Pack sizes: 30 tablets
50 tablets
60 tablets
120 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

A.Vogel Ireland Limited
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Dublin 10
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8 REGISTRATION NUMBER(S)

TR2309/003/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 9th December 2011
Date of last renewal: 8th December 2016

10 DATE OF REVISION OF THE TEXT

December 2022