

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **ATROSAN DEVIL'S CLAW TABLETS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Atrosan Devil's Claw tablets

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

One film-coated tablet contains 480mg of extract (as dry extract) from Devil's claw (Harpagophytum procumbens D.C. and/or H. zeyheri L. Decne.) root (1.5-3.0:1).

Extraction solvent: Ethanol 60% V/V.

For a full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

Film-coated tablet.

It is an oval-shaped, white coated tablet.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

A traditional herbal medicinal product used for the relief of backache, rheumatic or muscular pain, and general aches and pains in the muscles and joints, based on traditional use only.

#### **4.2 Posology and method of administration**

Adults and the elderly: 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.

For oral use only.

#### **4.3 Contraindications**

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

This product contains lactose. One film-coated tablet contains a maximum of 105 mg lactose.

Patients with rare hereditary problems of galactose

intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Patients under 18 years of age.

#### **4.4 Special warnings and precautions for use**

Do not exceed the stated dose.

If the condition worsens or symptoms persist for more than eight weeks, or if adverse effects not mentioned in the package leaflet occur, a doctor or a qualified health care practitioner 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 studies in animals have shown at high concentrations of Devil's claw possible calcium antagonistic effect similar to verapamil, caution should be taken when Devil's claw is administered to patients with cardiac disorders.

As a general precaution, patients with gastric or duodenal ulcer should not use Devil's claw preparations

#### **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 Pregnancy and lactation**

The safety of the product during pregnancy and lactation has not been established. In the absence of sufficient data the use during pregnancy and lactation is not recommended.

#### **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.

#### **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.

#### **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 anti-arthritic drugs of the NSAIDs.

## **5.2 Pharmacokinetic properties**

Non-clinical pharmacokinetic studies have not been conducted.

## **5.3 Preclinical safety data**

The non-clinical toxicology data available for Devil's claw is limited. Nonclinical studies to investigate reproductive toxicity and carcinogenicity have not been performed.

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**

For the tablet:

Lactose monohydrate

Maize starch

Cellulose, microcrystalline

Silica, colloidal anhydrous

Magnesium stearate (vegetable source)

Silica, precipitated

For the film coating:

Talc

Titanium dioxide

Macrogol

Hypromellose

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

36 months

#### **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

Keep out of the reach and sight of children.

#### **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

COC Blister packages with PP/COC/PP triple layer wells and aluminium foil sealing.

Pack sizes: 50 and 120 tablets.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal**

No special requirements.

### **7 MARKETING AUTHORISATION HOLDER**

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### **8 MARKETING AUTHORISATION NUMBER(S)**

THR 13668/0012

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

11/01/2008

### **10 DATE OF REVISION OF THE TEXT**

11/01/2008