

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

HARPADOL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 435 mg Devil's Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

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

For oral use only.

Adults and the elderly:

1 capsule morning, noon and evening during meals with a large glass of water.

The patient should consult a doctor if symptoms persist or do not improve after 8 weeks.

This product is not indicated in patients less than 18 years old (see section 4.4).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

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 8 weeks, or if adverse effects not mentioned in Section 4.8 occur, a doctor or 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.

Caution should be taken when Devil's claw is administered to patients affected by cardiovascular disorders.

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

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 the limited interaction studies, that Devil's claw will interact with other medicinal products.

4.6 Pregnancy and lactation

Safety 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 while taking Devil's claw. Affected patients should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pain.

Central Nervous system disorders: headaches, dizziness.

Skin disorders: allergic skin reactions (rash and itching).

The frequency is not known.

If other adverse effects not mentioned above occur, a doctor or qualified health care practitioner should be consulted.

4.9 Overdose

No case of overdose has been reported.

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

Mutagenicity/ Genotoxicity

A reverse mutation assay on bacteria indicated that *Harpagophytum* powder contained in HARPADOL was not found to be mutagenic in *Salmonella typhimurium* (strains TA 1535, TA 1537, TA98, TA 100) and *Escherichia coli* (strain WP2 pKM101/uvrA⁻) mutation assays with or without metabolic activation.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Silica colloidal hydrated
Hypromellose (capsule shell)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C
Store in the original package

6.5 Nature and contents of container

Brown polyvinyl chloride bottle of 45 or 150 capsules, with a security cap made of low-density polyethylene.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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