Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Harpadol Hard Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule (capsule).
Translucent colourless capsules filled with brown/yellow powder.

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 Oral Use

Adults and the elderly:
One capsule to be taken 3 times daily with a large glass of water.

Duration of use
For oral short-term use only
If the condition worsens, new symptoms develop or symptoms persist during the use of Harpadol, or for more than four weeks, a doctor should be consulted.
The safety of Harpadol in children and adolescents under 18 years of age has not yet been established as no data are available.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Pregnancy and breast-feeding.
The safety of Harpadol in children and adolescents under 18 years of age has not yet been established as no data are available.

4.4 Special warnings and precautions for use

Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor.
As a general precaution, patients with gastric or duodenal ulcers should not use Harpadol.

Some studies in animals have shown at high concentrations of Devil’s claw, possible calcium antagonistic effects similar to verapamil, caution should be taken when Devil’s claw is administered to patients with cardiac disorders.

If the symptoms worsen during the use of the medicinal product or if symptoms persist for more than 4 weeks, a qualified health care professional e.g. a doctor or pharmacist should be consulted.

Do not exceed the stated dose.

4.5 Interaction with other medicinal products and other forms of interaction

No noticeable interaction reported.

4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Devil's claw in pregnant women (see section 5.3). Harpadol 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. Harpadol 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

Gastrointestinal disorders: diarrhoea, nausea, vomiting, abdominal pain.
Nervous system disorders: headache, dizziness.
Skin and subcutaneous tissue disorders: allergic skin reactions.

The frequency is not known.

If other adverse reactions not mentioned above occur, a qualified health care professional e.g. a doctor or pharmacist should be consulted.

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

None reported. 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

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Colloidal hydrated silica
Hypromellose (capsule shell)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package to protect from light and moisture.

6.5 Nature and contents of container

Brown polyvinyl chloride container 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 REGISTRATION HOLDER

Laboratoires ARKOPHARMA
LID de Carros Le Broc – 1ère avenue, 2709 m
06510 Carros
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8 REGISTRATION NUMBER(S)

TR1450/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 23rd of March 2012.

Date of last renewal: 22nd March 2017

10 DATE OF REVISION OF THE TEXT

February 2018