SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Product name> film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 film-coated tablet contains 480 mg extract (as dry extract) of *Harpagophytum procumbens* D.C., radix (Devil´s claw), equivalent to 2.1 – 2.4 g root of Devil´s claw.
Extraction solvent: ethanol 60% (V/V)

Excipient(s) with known effect: Lactose monohydrate 226 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
Beige to light-brown oblong tablet
Dimensions:
- Length: 19.1 - 19.3 mm
- Width: 8.1 - 8.3 mm
- Height: 6.0 - 6.2 mm

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product used for relief of pain in mild osteoarthritis (OA).
The product is a traditional herbal medicinal product for use in the specified indication exclusively based on long-standing use.

4.2 Posology and method of administration

Posology
Adults: 1 tablet morning and evening.

Paediatric population
<Product name> is not recommended for children and adolescents under 18 years (see section 4.4. Special warnings and precautions for use).

Method of administration
The tablets should be taken with food and preferably with ½ glass of water. The tablets should be swallowed whole.

Duration of use
If the symptoms worsen or persist after 4 weeks of <Product name> treatment a doctor or other health care professional should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Gastric ulcer and duodenal ulcer.

4.4 Special warnings and precautions for use

The use in children and adolescents under 18 years of age is not recommended because of the lack of available experience.

Articular pain accompanied by swelling of joints, severe motion pain, redness or fever should be examined by a doctor.

Cautionshould be taken when administrated to patients with gallstone problems.

Caution should be taken when <Product name> is administrated to patients affected by cardiovascular disorders (see section 5.3 Preclinical safety data).

<Product name> contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Studies on possible effects on fertility are not available.
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.

4.8 Undesirable effects

Diarrhoea, nausea, vomiting and abdominal pain have been reported, as well as dizziness, headache and allergic skin reactions.
The frequency is not known.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after registration of the traditional herbal medicinal product is important. It allows continued monitoring of the safety of the traditional herbal medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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5.2 Pharmacokinetic properties

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5.3 Preclinical safety data

No mutagenic effect of <Product name> has been observed in Ames' test (with and without metabolic activation).
Other tests on genotoxicity and carcinogenicity or tests on reproductive toxicity have not been performed.

In some animal studies at high concentrations of a methanolic extract from Devil's claw, a calcium antagonistic effect, similar to that of verapamil, has been shown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Maize starch
Cellulose, microcrystalline
Silica, colloidal anhydrous
Magnesium stearate

Film coat:
Hypromellose
Talc
Titanium dioxide (E171)
Macrogol (6000)
Iron oxide, yellow (E172)
Iron oxide, brown (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Blister (Al/PVC/PVDC): 50, 60, 100, 120 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. REGISTRATION HOLDER

Dr. Loges + Co. GmbH
D-21423 Winsen
Germany

8. REGISTRATION NUMBER(S)

26897

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

08 May 2020