

SUMMARY OF PRODUCT CHARACTERISTICS

FLEXIHERB

1 NAME OF THE MEDICINAL PRODUCT

Flexiherb film-coated tablets
Jointlieve film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 film-coated tablet contains 600 mg of extract (as dry extract aqueous) from Devil's Claw root (*Harpagophytum procumbens*) (equivalent to 900-1500 mg of Devil's Claw root).

Excipients: 1 film-coated tablet contains 170mg of lactose monohydrate and 20 mg of sucrose

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.
White, oblong, smooth surface film coating without ruptures.

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 short term use only. The patient should consult a doctor if symptoms worsen or do not improve after 8 weeks.

For adults and the elderly, take 1 tablet twice daily. Take one dose in the morning and one in the evening. The dose can be increased to 2 tablets twice daily if the patient does not obtain relief after 3-5 days. Tablets should be swallowed whole with a little liquid. The tablets should not be chewed.

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

4.3 Contraindications

Active or previous gastric and/or duodenal ulcers.
Gallstones
Patients under 18 years of age.
Pregnancy
Lactation

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the condition worsens, or if symptoms persist for more than eight weeks, or if adverse effects not mentioned in the package leaflet occur, consult a healthcare practitioner.

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

This product contains sucrose.
1 film-coated tablet contains max. 20mg of sucrose or 0,031 carbohydrate units.

This product contains lactose.
1 film-coated tablet contains max. 170 mg lactose.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine

Some studies in animals have shown effects on the heart, blood pressure and blood glucose. The clinical significance of these findings is unknown. In patients with heart disease/arrhythmias, diabetes, or blood pressure problems this product should be used with caution.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs that inhibit platelet aggregation, anticoagulants, non-steroidal anti-inflammatory agents (including aspirin and COX-2 inhibitors):
There is a theoretical risk that concomitant administration with Devil's claw may increase the risk of bleeding..

4.6 Pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Therefore it should be avoided during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Some patients have experienced dizziness and somnolence while taking Devil's claw, which may affect the ability to drive and use machines.

4.8 Undesirable effects

Reports from clinical trials (18 studies with 2,219 patients treated with Devil's claw) show a cumulative incidence of adverse events of 4.4%. The most frequent adverse events (3.4%) were mild gastrointestinal complaints and included nausea and vomiting, constipation and diarrhoea, abdominal pain, flatulence, dyspepsia and heartburn. Mild allergic reactions were reported at an incidence of 0.31%. Other ADRs reported were tachycardia, cough, headaches, tinnitus, dizziness, somnolence and panic attacks. Their cumulative incidence was 0.59%.

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 definitively established. However, the iridoid glycoside 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 such as the NSAIDs.

5.2 Pharmacokinetic properties

A pharmacokinetic study involving 3 healthy male volunteers measured plasma harpagoside concentrations after oral administration of Devil's claw extract (WS1531 containing 9% harpagoside) 600, 1200 and 1800 mg as film coated tablets. Maximal plasma concentrations were reached after 1.3-1.8 hours, and were 8.2 ng/mL and 27.8 ng/mL for doses of harpagoside of 108 and 162 mg, respectively (corresponding to 1200 and 1800 mg Devil's claw extract, respectively). Plasma half life has been reported between 3.7 and 6.4 hours.

5.3 Preclinical safety data

The preclinical toxicology data available are limited. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, powdered
Lactose monohydrate
Sodium Starch Glycolate (Type A)
Silica, colloidal anhydrous
Magnesium stearate
Sucrose
Titanium dioxide E 171
Hypromellose
Cellulose, microcrystalline
Stearic acid.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life is 3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Original packages contain 30, 40, 60 and 80 film-coated tablets

FlexiHerb film-coated tablets are packed in PVC/ PVDC- aluminium blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER

THR 23056/0001

9 DATE OF FIRST REGISTRATION

To be advised

10 DATE OF REVISION OF THE TEXT