SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Giduxa soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
225 mg of extract (as dry extract) from *Harpagophytum procumbens* DC. and/or *Harpagophytum zeyheri* Decne. (devil's claw), radix (equivalent to 990-1125 mg of devil's claw root). Extraction solvent: ethanol 60% (V/V).

Excipients with known effect

Lactose monohydrate, 20 mg per capsule, corresponding to 19 mg lactose anhydrous.
Soya-bean oil, refined and lecithin (phospholipids from soya beans), 210 mg and 10 mg per capsule, respectively.
Sorbitol, approximately 27 mg per capsule.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, soft.

Oval (15x10 mm), light brown, soft capsules. The capsule contents are dark brown.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Giduxa is a traditional herbal medicinal product indicated:

- For the relief of minor articular pain.
- For the relief of mild digestive disorders such as bloating and flatulence and where there is temporary loss of appetite.

It is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

4.2 Posology and method of administration

Posology

Adults: Two capsules twice daily.
Maximum daily dose: four capsules.

Duration of use
If the symptoms persist longer than 4 weeks while using Giduxa for the relief of minor joint pain or 2 weeks for the relief of mild digestive disorders, a doctor or a qualified health care practitioner should be consulted.

Paediatric population
The safety and efficacy of devil's claw root in children and adolescents under 18 years of age has not been established (see section 4.4 'Special warnings and precautions for use').

Method of administration

Oral.

4.3 Contraindications

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

Active gastric or duodenal ulcer.

Giduxa contains refined soya-bean oil and lecithin (phospholipids from soya beans). Patients with peanut or soya allergies must not use this medicinal product.

4.4 Special warnings and precautions for use

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

Patients with gallstones should consult a physician before using Giduxa.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Giduxa contains lactose and sorbitol. Patients with rare hereditary problems of fructose or galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Paediatric population

The use of Giduxa in children and adolescents under 18 years of age is not recommended because of the lack of adequate data.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

No interactions have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy and breast-feeding

Safety during pregnancy and breast-feeding has not been established. In the absence of sufficient data, the use of Giduxa during pregnancy and lactation is not recommended.

Fertility

No fertility data available.

4.7 Effects on ability to drive and use machines

Giduxa has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following adverse reactions have been reported. The frequency is not known.

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

Central nervous system effects: headache, vertigo.

Hypersensitivity reactions: e.g. rash, hives, facial oedema.

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the safety of the 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 devil's claw has been observed in an Ames test (with and without metabolic activation).

Tests on reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule fill:
Lactose monohydrate
Hydrated colloidal silica
Refined soya-bean oil
Refined coconut oil
Fractionated palm kernel oil
Yellow beeswax
Lecithin (phospholipids from soya beans)
Butter fat

Capsule shell:
Gelatin
Glycerol
Partially dehydrated liquid sorbitol (E420)
Yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

PVC/PVDC-Aluminium blisters in an outer carton.
Pack sizes: 30, 60, 90 and 120 capsules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. REGISTRATION HOLDER

[To be completed nationally]

8. REGISTRATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: [To be completed nationally]
Date of latest renewal: [To be completed nationally]

10. DATE OF REVISION OF THE TEXT

8 December 2022