SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Glitinum, hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
100 mg of powdered *Tanacetum parthenium* (L.) Schulz Bip., (feverfew), herba corresponding to 100 mg of dried herb of feverfew.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard capsule

White opaque hard capsule (19.4x7.0 mm). The capsule contents are beige-greenish.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product indicated for the prophylaxis of migraine headaches after serious conditions have been excluded by a medical doctor.

The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2 Posology and method of administration

Posology

Adults and elderly
One capsule daily.

Paediatric population
The use of Glitinum in children and adolescents under 18 years of age is contraindicated (see section 4.3).

Method of administration

Oral use: Capsules should be swallowed whole (with water or a little liquid). The capsules should not be chewed.

Duration of use

If migraine headaches recur after using the medicinal product for 2 months (usual period of treatment to obtain an effect), a doctor or a qualified health care practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or other plants of the Asteraceae (Compositae) family or to any of the excipients listed in section 6.1.

Paediatric population
The use in children and adolescents under 18 years of age is contraindicated due to lack of adequate data.

4.4 Special warnings and precautions for use

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

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. However, traditional experience suggests that *Tanacetum parthenium* may stimulate menstrual flow and induce abortion. In addition, studies in animals have shown reproductive toxicity after high doses of feverfew (see section 5.3).
In the absence of sufficient data, the use of Glitinum during pregnancy and lactation is not recommended.

Fertility

There are no data on the effects of feverfew on male and female fertility.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Gastrointestinal disturbances have been reported. The frequency is not known.

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 authorisation 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

Pharmacotherapeutic group: Other antimigraine preparations, ATC code: N02CX

5.2 Pharmacokinetic properties

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5.3 Preclinical safety data

A single study with oral administration of feverfew in high dose (839 mg/kg bw) in pregnant rats showed maternal toxicity and embryotoxicity. However, adequate studies on reproductive toxicity have not been performed.

No mutagenic effect of feverfew has been observed in Ames test (with and without metabolic activation).

Tests on carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule fill:
Dextrin
Silica, colloidal anhydrous
Talc
Magnesium stearate

Capsule shell:
Titanium dioxide E 171
Hypromellose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

PVC/PVDC aluminium blisters in an outer carton.
Pack sizes: 30, 60, 90 or 120 hard 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: {DD month YYYY}
Date of latest renewal: {DD month YYYY}

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]
2024-06-07