

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

DiaMigraine Hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 hard capsule contains:
100mg Feverfew herb (*Tanacetum parthenium*).

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Hard white capsule.

4 CLINICAL PARTICULARS

4.1 *Therapeutic indications*

A traditional herbal medicinal product used for the prevention of migraine headaches 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 12 weeks.

For adults and the elderly, take one capsule daily. Capsules should be swallowed whole with water or a little liquid. The capsules should not be chewed.

This product should be taken continuously for three months in order to achieve maximum benefit.

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

4.3 *Contraindications*

Hypersensitivity to any of the ingredients or to Feverfew, chrysanthemums, daisies, marigolds, or other members of the Asteraceae (Compositae) family, including ragweed.

Due to lack of data this product is contraindicated in children and adolescents under 18 years.

4.4 *Special warnings and precautions for use*

Do not exceed the stated dose.

Patients who take Feverfew for migraine should have been previously diagnosed by a doctor of this condition. If the patient experiences changes in the migraines (i.e. increase in attacks, worsening of pain, new symptoms) they should be instructed to consult their doctor.

Long-term Feverfew users who stop treatment suddenly may experience withdrawal symptoms, including rebound headaches, anxiety, difficulty sleeping, muscle stiffness, and joint pain. Patients who are on long term therapy with Feverfew should be instructed to seek professional advice before stopping treatment.

Evidence from a limited number of in vitro studies suggests that feverfew may inhibit platelet function, the relevance of this in humans is unknown.

4.5 *Interaction with other medicinal products and other forms of interaction*

Drugs that affect coagulation and bleeding:

Feverfew theoretically may increase the risk of bleeding when taken with drugs that affect coagulation and bleeding. Some examples include aspirin, anticoagulants such as warfarin or heparin, anti-platelet drugs such as clopidogrel, and non-steroidal anti-inflammatory drugs such as aspirin, ibuprofen and naproxen.

4.6 *Pregnancy and lactation*

There are no adequate data of the use of Feverfew in pregnancy and lactation.

However, traditional experience suggests that Feverfew may stimulate menstrual flow and induce abortion. As a general precaution, use is not recommended in pregnancy.

It is not known whether Feverfew is excreted in the milk or not. As a general precaution, use is not recommended during lactation.

4.7 *Effects on ability to drive and use machines*

No data on the effects on the ability to drive and use machines are available.

4.8 *Undesirable effects*

The review of the adverse drug reactions reported in clinical trials indicate that most side-effects are mild and reversible.

Mouth inflammation or ulcers, including swelling of the lips, tongue irritation, bleeding of the gums, and loss of taste have been reported, usually after direct contact of the mouth with the leaves, although some people report burning after swallowing a capsule containing dried leaf.

Photosensitivity (sensitivity to sunlight or sunlamps) has been reported with other herbs in the Asteraceae (Compositae) plant family (see Section 4.4).

Indigestion, nausea, flatulence, constipation, diarrhoea, abdominal bloating, and heartburn have been reported rarely.

Feverfew can also cause allergic rashes.

Increased heart rate in some patients has been reported in one small study.

Other side effects that have been reported spontaneously are eosinophilia, abnormal liver function tests, arthritis, renal failure, Raynaud's phenomenon and hypertension.

These were spontaneously generated adverse drug reactions during post-marketing surveillance and the causal relation to Feverfew cannot be established.

4.9 Overdose

There are well documented cases of overdose with Feverfew. In cases of overdose the treatment should be supportive. Since there is a theoretical increased risk of bleeding, patients should be closely monitored for signs of bleeding.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anti-migraine preparations, ATC: N02CX.

Preclinical studies suggest that Feverfew may inhibit the secretion of serotonin from blood platelets, and may have anti-inflammatory and vascular effects (inhibition of vasoconstriction). Clinical studies have not demonstrated any effect in vivo on the secretion of serotonin but indicate that Feverfew may relieve the pain associated with migraines and other types of headaches.

5.2 Pharmacokinetic properties

There is no pharmacokinetic data available

5.3 Preclinical safety data

The preclinical toxicology data available are limited. There are no repeat-dose toxicity data available. Appropriate tests on genotoxicity and carcinogenicity have not been performed.

In two small teratogenicity studies, pregnant rats were administered very high doses of Feverfew (0.86 g/kg/day) as an ethanolic extract; this dose represents the highest possible for which ethanol remained below the teratogenic threshold. Results showed that extracts of Feverfew induced both maternal and embryotoxic effects of reduced foetal weights with Feverfew administered from day 8 to 15 of gestation, and enlarged placentae on administration of Feverfew from day 1 to 8, or day 8 to 15.

However, the percentages of implantation loss and litter size were not significantly different from controls.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dextrin, white
Silica, colloidal anhydrous
Talc
Magnesium stearate
Titanium dioxide E171
Hypromellose

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 containing 30, 60, 90 or 100 hard capsules

DiaMigraine capsules are packed in PVC/ PVDC aluminium blisters and inserted into a carton.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Diapharm Regulatory Services GmbH
Würzburger Str. 3
26121 Oldenburg
Germany

8 MARKETING AUTHORISATION NUMBER(S)

THR 33518/0013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/07/2009

10 DATE OF REVISION OF THE TEXT

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