

PADMA DIGESTIN

PADMA AG

Capsules

Tibetan medicinal product

Composition

Active substances: Pulvis ex Punicae granati semen, Galangae rhizoma, Piperis longi fructus, Cardamomi semen, Cinnamomi cassiae cortex.

Excipients: Highly dispersed silicon dioxide, silicated microcrystalline cellulose.

Padma Digestin is also suitable for diabetics. One capsule contains 0.09 g utilisable carbohydrate.

Dosage form and amount of active substances per unit

Capsule shell: hydroxypropyl methylcellulose.

Pulvis ex Punicae granati semen 204 mg, Galangae rhizoma 102 mg, Piperis longi fructus 25.5 mg, Cardamomi semen 12.75 mg, Cinnamomi cassiae cortex 12.75 mg.

Indications / therapeutic use

According to the Tibetan consideration this formula enhances digestion. PADMA DIGESTIN is traditionally used when digestion tends to be poor and in digestive disorders, which can be manifested as feelings of pressure or fullness in the stomach area, and flatulence. Padma Digestin is also used for poor appetite, (e.g. during re-coalescence).

Dosage / application

Adults (from 18 years): 2-3 capsules are taken in the morning, together with ample fluid. In more persistent cases, an additional dose of 2-3 capsules can be taken in the evening. For acute symptoms after a large meal, 2-3 capsules are recommended. The maximum daily dose is 6 capsules.

The best results are achieved if the capsules are taken on an empty stomach, with preferably warm fluid. Persons with difficulties in swallowing should suspend the contents of the capsules in warm water.

For acute symptoms, short term treatment is adequate. On the other hand, in cases of poor digestion, lack of appetite or fatigue the product can be taken for several weeks.

It is not recommended to use PADMA DIGESTIN in children or adolescents under 18 years, as there are no clinical data.

Contraindications

Hypersensitivity to one of the active ingredients or to one of the excipients according to the composition.

Due to nonexistent studies the use of PADMA DIGESTIN is not recommended in children and adolescents.

Warnings and precautions

Interactions with other medicines cannot be excluded (see 'Interactions').

Interactions

There have been no reports of interactions with other medicines.

In vitro studies in human liver microsomes have been performed with a methanolic extract of PADMA DIGESTIN. These have shown that the extract inhibits CYP 1A2, CYP 2C9 and, to a lesser extent, CYP 2C19. No clinical studies have been performed. The simultaneous use of medicines metabolized by CYP 1A2, CYP 2C9 or CYP 2C19 (e.g. for CYP 1A2: clozapine, imipramine, naproxen, olanzapine, ropinirole, tacrine, theophylline, tizanidine etc.; for CYP 2C9: tolbutamide, cimetidine, diclofenac, ibuprofen, warfarin, phenytoin, losartan, tamoxifen, etc.; for CYP 2C19: amitriptyline, carbamazepine, clopidogrel, diazepam, lansoprazole, omeprazole, phenobarbital, progesterone, etc.), could lead to increased substrate concentrations after administration of normal doses. Patients taking one of these medicines together with PADMA DIGESTIN should be carefully monitored.

Pregnancy / breast-feeding

The active substances are everyday spices and foods. It can be assumed that the number of expositions of pregnant and breast-feeding women is high. Animal studies with the individual active substances have found no evidence for reproduction toxicity (see 'Preclinical data'). On the other hand, there are no adequate epidemiological data on the effects of PADMA DIGESTIN on pregnancy, the development of the embryo and fetus, or birth or postnatal development. When used during pregnancy and lactation caution is advised.

Effects on ability to drive and use machines

No relevant studies have been performed.

Undesirable effects

No undesirable effects have been reported after use of PADMA DIGESTIN in accordance with instructions.

Overdosage

No cases of overdosage have been reported.

Properties / Effects

ATC-Code: A16AX

Mechanism of action

PADMA DIGESTIN contains a complex of herbal active ingredients, prepared according to the concept of Tibetan medicine.

Clinical efficacy

The use of PADMA DIGESTIN is solely based on experience. No data are available from clinical studies.

Pharmacokinetics

No relevant studies have been performed.

Preclinical data

An *in vivo* study on genotoxicity found no risk potential. No studies on carcinogenicity or reproduction toxicity have been performed with PADMA DIGESTIN. Carcinogenicity studies with extracts or isolated constituents of individual active substances - oil from *Punicae granati*

semen, coumarin, cinnamaldehyde - have found no risk potential for humans. Studies on rats and mice with extracts or isolated components of individual active substances – Piperis longi fructus and extracts, piperine, extract of Cinnamomi cassiae cortex and cinnamaldehyde - have found no evidence for reproduction toxicity, including fertility, teratogenicity, peri- or postnatal toxicity, at the doses contained in PADMA DIGESTIN.

Additional information

Incompatibilities

Not applicable

Interference with diagnostic methods

None known

Shelf life

The medicine may only be used up to the date marked with “EXP”.

Special precautions for storage

Store in the original packaging at room temperature (15–25 °C).

Store out of the reach of children.

Notes on handling

Not applicable

Marketing authorization number

59375 (Swissmedic).

Packages

20 capsules (D)

60 capsules (D)

Marketing authorization holder

PADMA AG, Haldenstrasse 30, CH-8620 Wetzikon.

Manufacturer

PADMA AG, Haldenstrasse 30, CH-8620 Wetzikon.

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