

PADMA 28

PADMA AG

Capsules

Tibetan medicinal product

Composition

Active substances: Pulvis ex Aegle sepiar fructus 20 mg, Aquilegiae vulgaris herba 15 mg, Aucklandiae radix 40 mg, Calcii sulfas hemihydricus 20 mg, Calendulae flos cum calyce 5 mg, Cardamomi fructus 30 mg, Caryophylli flos 12 mg, D-Camphora 4 mg, Kaempferiae galangae rhizoma 10 mg, Lactucaae sativae folium 6 mg, Lichen islandicus 40 mg, Liquiritiae radix 15 mg, Meliae tousend fructus 35 mg, Myrobalani fructus 30 mg, Pimentae fructus 25 mg, Plantaginis lanceolatae folium 15 mg, Polygoni avicularis herba 15 mg, Potentillae aureae herba 15 mg, Santali rubri lignum 30 mg, Sidae cordifoliae herba 10 mg, Aconiti tuber 1 mg, Valerianae radix 10 mg (standardised to 4 mg D-camphor and at least 1.7% [V/m] in the capsule contents).

Excipients

Capsules: Silica, colloidal anhydrous

PADMA 28 capsules are also suitable for diabetics. They do not contain lactose and are gluten-free.

Dosage form and amount of active substances per unit

Hard gelatine capsules, 403 mg.

Indications / therapeutic use

PADMA 28 is effective in circulatory disorders with symptoms such as a tingling sensation, formication, feeling of heaviness and tension in the legs and arms, numbness of the hands and feet and calf cramps.

Dosage / application

Adults: Two capsules 3 times a day, taken with ample fluid before or during meals is the recommended initial dosage. When there is definite improvement the dosage can be reduced to 1 to 2 capsules per day. Persons who have difficulty with swallowing should suspend the contents of the capsules in lukewarm water. If gastrointestinal symptoms appear, the capsules may be taken during the meal, with ample fluid (preferably with lukewarm water).

Between the intake of PADMA 28 and other medicines, an interval of one and a half to two hours has to be observed.

Children: The use and safety of PADMA 28 have not been studied in children and adolescents and, due to its intended use there is no relevant indication in children.

Contraindications

Hypersensitivity to one of the active ingredients or to one of the excipients listed in the composition. Due to non-existent studies the use of PADMA 28 is not recommended in children and adolescents.

Warnings and precautions

None known.

Interactions

To date no interactions with other medicines are known.

Pregnancy / breast-feeding

There are no clinical data available on the use of the product in pregnant women and no adequate experimental studies in animals on the effect on pregnancy, embryonic development, development of the foetus and postnatal development. The potential risk for humans is not known.

Caution is advised when used during pregnancy.

Effects on ability to drive and use machines

No studies have been carried out in this respect.

Unwanted effects

Gastrointestinal disorders: very rare.

Nervous disorders with palpitations and slight restlessness in predisposed individuals: very rare.

Cutaneous reactions or itching: very rare

Overdosage

No cases of overdosage have been reported.

Properties / Effects

ATC-Code: C01EX

Mechanism of action

PADMA 28 is a medicinal product that is manufactured in Switzerland according to a proven Tibetan formulation.

It contains a complex, mainly plant-based active substance mixture, which is composed of primary and secondary components according to the principles and knowledge of Tibetan medicine: the secondary components modulate the effects of the primary components and mitigate any unwanted effects.

The individual components are present in low doses and achieve the therapeutic effect in an additive, synergistic and antagonistic manner.

The active substance contains, among others the following groups of relevant constituents which according to reports in the literature have the following effects: essential oil with the primary component D-camphor (stimulates the blood circulation and improves the work tolerance in higher doses), eugenol (antibacterial and locally analgesic), flavonoids (anti-inflammatory, antioxidative, metal chelating effects) and tannins (locally anti-inflammatory, antioxidative).

Clinical efficacy

A significant and clinically relevant increase in the maximum and the pain-free walking distance has been demonstrated in patients with peripheral arterial occlusive disease (Fontaine stage II). Furthermore an improvement in some parameters of haemodynamic

function (“ischaemic window“, derived from the exercise-induced, percental drop of the arterial ankle pressure and the recovery time of this pressure after exercise) has also been observed.

Pharmacokinetics

Because of the complex composition of the active substances, no pharmacokinetic studies have been conducted.

Preclinical data

Experimental animal studies of single dose and repeated dose toxicity and in vitro studies of genotoxicity showed no potential risk.

Additional information

Incompatibilities

Not applicable.

Effect on diagnostic measures

None known

Shelf life

The medicinal product may only be used up to the date indicated with “EXP” on the package.

Special storage instructions

Store in original package at room temperature (15 - 25°C).

Store out of the reach of children.

Instructions for handling

Not applicable.

Marketing authorisation number

58436 (Swissmedic).

Packages

PADMA 28 caps 60. (D)

PADMA 28 caps 200. (D)

PADMA 28 caps 540. (D)

Marketing authorisation holder

PADMA AG, Haldenstrasse 30, CH-8620 Wetzikon.

Manufacturer

PADMA AG, Haldenstrasse 30, CH-8620 Wetzikon.

Information as of

July 2008.