

# Padma® 28

PADMA

*Tibetan medicinal product*

## **AMZV**

### **Composition**

#### *Active substances:*

Aegle sepiar fructus 20 mg, Amomi fructus 25 mg, Aquilegiae vulgaris herba 15 mg, Calcii sulfas pulvis 20 mg, Calendulae flos cum calyce 5 mg, Cardamomi fructus 30 mg, Caryophylli flos 12 mg, Costi amari radix 40 mg, D-Camphora 4 mg, Kaempferiae galangae rhizoma 10 mg, Lactuciae sativae folium 6 mg, Lichen islandicus 40 mg, Liquiritiae radix 15 mg, Meliae tousend fructus 35 mg, Myrobalani fructus 30 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 1.2% [V/m] essential oil in the tablets or 1.5% [V/m] in the capsule contents).

#### *Excipients*

*Tablets:* sorbitol; silica, colloidal anhydrous

*Capsules:* silica, colloidal anhydrous

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

### **Dosage form and amount of active substances per unit**

Tablets, 403 mg

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.

### **Posology/Application**

*Adults:* Two tablets or capsules 3 times a day, taken with ample fluid 30 minutes to 1 hour before meals is the recommended initial dosage. As soon as there is definite improvement the dosage can be reduced to 1 to 2 tablets or capsules per day. Persons who have difficulty swallowing should suspend the tablets or the contents of the capsules in lukewarm water. If gastrointestinal symptoms appear, the tablets or the capsules may be taken at mealtimes, with ample fluid (preferably boiled, lukewarm water).

An interval of one-and-a-half to two hours must be allowed between taking PADMA 28 and other drugs.

*Children:* The use and safety of PADMA 28 has not been studied in children and youths; there is no relevant indication for use of the product in children.

### **Contraindications**

Hypersensitivity to one of the active ingredients or to one of the excipients listed in the composition.

### **Warnings and precautions**

None known.

### **Interactions**

Up till now, no interactions with other drugs are known.

### **Pregnancy and 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, embryonal development, development of the foetus and postnatal development. The potential risk for humans is not known.

Caution is indicated with the use of the product 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

### **Overdose**

No cases of overdose 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 recipe.

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 cushion 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 other constituents, 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 circulation and improves the work tolerance when taken in higher doses), eugenol (antibacterial and locally analgesic), flavonoids (antiinflammatory, antioxidative, forming metallic chelates) and tannins (locally antiinflammatory, 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 (Stage II, according to Fontaine). An improvement in some parameters of haemodynamic function (“ischaemic window“, derived from the exercise-induced 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 carried out.

### **Preclinical safety data**

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

**Other instructions**

*Incompatibilities*

Not applicable.

*Effect on diagnostic measures*

None known

*Shelf life*

Tablets: 5 years

Capsules: 3 years

*Special storage instructions*

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

*Instructions for handling*

Not applicable.

**Marketing authorisation number**

41125, 58436 (Swissmedic)

**Marketing authorisation holder**

PADMA AG, Wiesenstrasse 5, 8603 Schwerzenbach, Switzerland

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