

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME

**ARCALION 200 mg, coated tablet**

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Box of 10, 20 and 30 coated tablets.

Not all pack-sizes may be marketed.

	<i>per tablet</i>
Sulbutiamine (INN) .....	200 mg

Excipients: white beeswax, ethylcellulose, anhydrous glucose, glycerol mono-oleate, lactose monohydrate, magnesium stearate, maize starch; starch, polysorbate 80, povidone, colloidal anhydrous silica, sodium hydrogen carbonate, sucrose, talc, titanium dioxide (E 171), carmellose sodium, sunset yellow FCF (E 110) aluminium lake.

### 3. PHARMACEUTICAL FORM

Coated tablet.

### 4. CLINICAL DATA

#### 4.1 Therapeutic indications

Treatment of certain physical or mental inhibition states involving reduced activity and apathy. In confirmed depressive states, this medicine does not eliminate the need for specific antidepressant treatment.

#### 4.2 Dosage and method of administration

FOR ADULT USE ONLY.

2 to 3 tablets a day.

Tablets should be swallowed whole with a large glass of water, dividing the doses between the morning and midday meals.

Duration of treatment is limited to 4 weeks.

#### 4.3 Contra-indications

This drug is contra-indicated in the case of:

- Past history of hypersensitivity to one of the ingredients of the tablet.

#### 4.4 Warnings and special precautions for use

Due to the presence of lactose, this drug is contra-indicated in the case of congenital galactosemia, the syndrome of malabsorption of glucose and galactose or a deficit in lactase.

#### 4.5 Interactions with other drugs and other types of interactions

Not applicable

#### 4.6 Pregnancy and lactation

In consideration of the available data and clinical follow-up, it is preferable not to use sulbutiamine during pregnancy whatever the term.

Due to the absence of data concerning the excretion of this drug in breast milk, its use should be avoided in breastfeeding women.

#### 4.7 Effects on the ability to drive vehicles and use machinery

Not applicable.

#### 4.8 Side effects

Possibility of neuro-psychic side effects (tremor, malaise, headaches, agitation), of skin allergy and digestive disorders.

Due to the presence of sunset yellow FCF, risk of allergic reactions.

#### 4.9 Overdosage

In cases of massive absorption, there may be agitation with euphoria and tremor of the extremities.

These symptoms are transient and are rapidly resolved.

### **5. PHARMACOLOGICAL PROPERTIES**

#### 5.1 Pharmacodynamic properties

PSYCHOSTIMULANT

(N : nervous system)

In man :

This drug has been studied in controlled clinical trials versus placebo or reference products, by using psychometric evaluation scales and tests. These trials demonstrate the psychoactive effect of this drug, with a predominant action on psychological and physical inhibition.

#### 5.2 Pharmacokinetic properties

Sulbutiamine is rapidly absorbed and peak blood concentrations are reached between 1 and 2 hours after administration.

The half-life is approximately 5 hours. Elimination is by the urinary route.

#### 5.3 Preclinical safety data

Not applicable.

### **6. PHARMACEUTICAL DATA**

#### 6.1 Incompatibilities

Not applicable

6.2 Shelf-life

24 months

6.3 Special storage precautions

Store up to 30°C.