arcalion®
sulbutiamine

COMPOSITION

Each sugar-coated tablet contains 200 mg of sulbutiamine.

INDICATIONS

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

DOSAGE AND 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.

CONTRA-INDICATIONS

Hypersensitivity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS

This medicinal product contains lactose, glucose and sucrose. This medicine should not be used by patients with galactose or fructose intolerance, Lapp lactase deficiency or glucose and galactose malabsorption syndrome (rare hereditary diseases) or a sucrase/isomaltase deficiency.
This medicine contains an azo colouring agent (E110) and may provoke allergic reactions.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

No specific interaction studies have been performed with ARCALION.

Concomitant use to be taken into consideration:

- Diuretics:
  The urinary excretion of thiamine (metabolite of sulbutiamine) is increased.
- Neuromuscular blocking agents:
  The effect of these medicines may be increased when administered concomitantly with thiamine (metabolite of sulbutiamine).

FERTILITY, PREGNANCY AND BREASTFEEDING

Pregnancy
There is no or limited data available (less than 300 pregnancy outcomes) on the use of sulbutiamine in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of ARCALION during pregnancy.

Breastfeeding
It is unknown whether sulbutiamine/metabolites are excreted in human milk.
A risk to the newborns/infants cannot be excluded.
ARCALION should not be used during breast-feeding.

Fertility
There is no available data regarding the effects of sulbutiamine on fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No specific studies on the effect on ability to drive and to use machines have been performed.

UNDESIRABLE EFFECTS

Tabulated list of undesirable effects
The following undesirable effects or events have been reported and are ranked using the following frequency: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated form the available data).

MedDRA system organ class	Frequency	Undesirable effects
Psychiatric disorders	Uncommon	Agitation
Nervous system disorders	Uncommon	Headache
		Tremor
Gastrointestinal disorders	Uncommon	Nausea
		Vomiting
	Not known	Gastralgia
		Diarrhoea
Skin and subcutaneous tissue disorders	Uncommon	Rash
General disorders and administration site conditions	Uncommon	Malaise

Description of selected undesirable effects
Due to the presence of sunset yellow FCF (E110), risk of allergic reactions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the

benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via PUSAT FARMAKOVIGILANS-BPOM: Tlp. 021-4245459, 021-4244755 Ext. 111, Fax. 021-4243605, 021-42885404; Email: pv-center@pom.go.id and/or Indonesia-MESO-BadanPOM@hotmail.com.

OVERDOSAGE

Symptoms
In case of overdose: agitation with euphoria and tremor of the extremities.
These symptoms are transient.

Treatment
Overdose symptoms can be treated according to the doctor's assessment.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties
Pharmacotherapeutic group: Vitamin B1, plain, ATC code: A11DA02

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

Pharmacokinetic Properties
Sulbutiamine is rapidly absorbed and the peak blood concentration is reached between one and two hours after administration.
The half-life is about five hours.
The elimination is urinary.

Preclinical safety data
No special hazards have been identified for use in humans on the basis of preclinical studies of acute, subchronic and chronic toxicity and reproduction toxicity (studies conducted in pregnant mice, rats and rabbits haven't shown any teratogenic potential). Sulbutiamine was not mutagenic in the Ames test. No studies of carcinogenicity have been performed.

STORAGE

Store at below 30°C
Shelf life : 2,5 years

PRESENTATION

Box of 60 sugar-coated tablets in 10 strips of 6 tablets

Reg. No. : DKL1704525616A1

HARUS DENGAN RESEP DOKTER

Manufactured by :
PT. Darya-Varia Laboratoria Tbk
Bogor - Indonesia

Under license of :
SERVIER
Les Laboratoires Servier-France

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