Arcalion 200 mg

Sulbutiamine

COMPOSITION

SULBUTIAMINE……200 mg
Excipients……q.s.f one coated tablet

LIST OF EXCIPIENTS

Maize starch, starch paste, anhydrous glucose, lactose monohydrate, magnesium stearate, talc, sodium hydrogen carbonate, carmellose sodium, white beeswax, titanium dioxide (E 171), ethylcellulose, sunset yellow FCF aluminium lake (E 110), glycerol monooleate, polysorbate 80, povidone, sucrose, colloidal anhydrous silica (Aerosil 130).

PHARMACEUTICAL FORM

Box of 30 coated tablets.

THERAPEUTIC INDICATION

Certain states of transient fatigue in adults (over 15 years old).

CONTRAINDICATIONS

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

If in doubt, you must ask your physician or your pharmacist for advice.

SPECIAL WARNINGS

This product contains glucose, lactose and sucrose. Patients with rare hereditary problems of fructose or galactose intolerance, the Lapp lactase deficiency or sucrose-isomaltase insufficiency, or glucose-galactose malabsorption should not take this medication.

This medicinal product contains sunset yellow FCF (E-110) and may cause allergic reactions.

PRECAUTIONS

If symptoms persist for more than 4 weeks, consult your physician.

If in doubt, do not hesitate to consult your physician or your pharmacist for advice.

DRUG INTERACTIONS AND OTHER INTERACTIONS

No specific interaction studies have been performed with sulbutiamine.

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 jointly with thiamine (metabolite of sulbutiamine).

PREGNANCY AND BREAST FEEDING

The use of this drug should generally be avoided during pregnancy.

Inform your physician in case of pregnancy during treatment; only your physician can judge the need to continue the treatment.

The use of this drug should be avoided in breast feeding women.

As a general rule, if you are pregnant or breast feeding you should always seek the advice of your physician or pharmacist before taking a medication.

DOSAGE

For adult use only – Oral route.
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.

This drug has been dispensed to you personally in a specific situation:

- *It cannot be adapted to another case,*
- *Do not recommend it to another person*

OVERDOSE

Agitation with euphoria and tremor of the extremities may be experienced.
These symptoms are transient.

You should consult a doctor in the event of an overdose.

ADVERSE EFFECTS

Like any active substance, in some individuals this drug may induce unpleasant effects of varying severity:

- Possibility of skin allergy, gastrointestinal disorders such as upper abdominal pain and diarrhea at an unknown frequency, nausea, vomiting, agitation, headaches, tremor and malaise
- Due to the presence of sunset yellow FCF, risk of allergic reactions.

Tell your physician or your pharmacist if you experience any undesirable and unpleasant effects which are not mentioned in this leaflet.

SHELF LIFE

Do not exceed the expiry date printed on the box.

STORAGE CONDITIONS

Store below 30°C.

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