Enerion®

International Non-Proprietary Name (INN): Sulbutiamine

Dosage Form: tablets

Structure: 1 tablet contains:
Active ingredient: sulbutiamine 200mg.
Excipients: corn starch; dried starch paste; anhydrous glucose (dextrose); lactose monohydrate; magnesium stearate; talc, *Capsule shell composition:* sodium hydrocarbonate; sodium carboxymethylcellulose; white beeswax; titanium dioxide (E171); ethylcellulose; "Sunset" yellow FCF, E110; glycerol monooleate; polysorbate 80; povidone; sucrose; colloidal anhydrous silicon dioxide (Aerosil 130), talc.

Description: double-radius, round tablets with an orange shell; a slight surface (the level of glossiness) or colour inhomogeneity is permitted, insignificant impregnations are allowed.

Pharmacological Classification: medicine, regulating metabolic processes in the central nervous system

ATX Code: A11DA02

Pharmacological Action: regulation of metabolic processes in the central nervous system

Pharmacodynamics:
Enerion is a synthetic substance; its structure is close to thiamine, compared to which the molecule has an open thiazole cycle, an additional disulphide bond, and a lipophilic ether. Due to this modification, Sulbutiamine is well soluble in fat; it is quickly absorbed from the digestive tract and easily penetrates into the blood-brain barrier (BBB). In contrast to thiamine, it can accumulate in the cells of the reticular formation, in the hippocampus and the dentate gyrus, as well as in the Purkinje cells and in the glomeruli of the granular layer of the cerebellar cortex. Enerion improves the coordination of movement and resistance to physical exercise, the stability of the cerebral cortex structures becomes more resistant to a repeated anoxia. The medicine is effective for the symptomatic treatment of functional asthenia.

Pharmacokinetics:
Sulbutiamine is quickly absorbed from the gastro-intestinal tract. The maximum concentration in blood plasma is reached 1-2 hours after an intake. The half-life is about 5 hours. The medicine is excreted in the urine.

Intended Uses:
Symptomatic treatment of functional asthenia.

Contraindications:
Hypersensitivity to Enerion ingredients.
The medicine is not recommended for patients under 18 years old (due to the lack of clinical data).
Lactose monohydrate is one of Enerion's excipients. Hence, the medicine is not recommended for patients with lactose insufficiency, galactosemia or glucose/galactose malabsorption syndrome.

Dosage and Administration:
Per os. Enerion is recommended for adult patients only.
The daily dose is 2-3 tablets (400-600 mg) divided into 2 intakes (during breakfast and lunch). Duration of treatment should not exceed 4 weeks.

Side Effects:
Allergic reactions (presence of "Sunset" yellow in the composition of the medication), digestive disorders, psychoneurological

reactions (tremor, headache, agitation, general malaise).

Overdose:
Excitement with symptoms of euphoria and tremor of extremities. These symptoms are transient and do not require special treatment.

Interaction with Other Drugs:
There is no interaction with other medicines.

Pregnancy and Lactation:
According to the results of clinical studies, the medicine does not affect the foetation. However, due to the lack of sufficient clinical data, Enerion is not recommended during pregnancy and lactation.

Influence on the Ability to Drive Vehicles and Mechanisms:
The medicine has no effect on the ability to drive vehicles and mechanisms.

Terms of Release From Pharmacy: on prescription

Storage Conditions: at a temperature of no higher than 25°C. Keep out of the reach of children.

Shelf Life: 3 years. Do not use beyond the expiration date.

Country of Manufacture: France