PRESCRIBING INFORMATION

TIVORTIN® ASPARTATE
(TIVORTIN ASPARTATUM)

Qualitative and quantitative composition of the medicinal product:
active ingredient: 1 mL solution contains 200 mg L-arginine aspartate;
excipients: sorbitol (E420), sodium saccharine (E 954), methyl parahydroxybenzoate (E 218), propylparahydroxibenzoate (E 216), caramel food flavoring, purified water.

Pharmaceutical form.
Oral solution.

Pharmacotherapeutic group.
Other cardiological agents. Amino acids. ATC code – C01E.

Clinical particulars.
Therapeutic indications.
Combination therapy of ischemic heart disease, arteriosclerotic heart disease and cerebral atherosclerosis, hypertension, atherosclerotic peripheral vascular disease, diabetic angiopathy, conditions after acute myocardial infarction and acute cerebrovascular accident, myocardiopathy, chronic heart failure, hypercholesterolemia, chronic obstructive pulmonary diseases, interstitial pneumonia, idiopathic pulmonary hypertension, chronic postembolic pulmonary hypertension, acute and chronic hepatitis of various etiology, hepatic failure, hepatic encephalopathy due to hyperammoniemia, hypoxic states and asthenia, immune correction in impaired thymic function.

Contraindications.
Hypersensitivity, severe renal impairment, children (aged under 18).

Posology and method of administration.
Administered orally during meals. In ischemic heart disease, arteriosclerotic heart disease and cerebral atherosclerosis, atherosclerotic peripheral vascular disease, diabetic angiopathy the dose for adults is 5 mL (1 measuring spoon – 1 g of medicine) taken 3-8 times a day. In hypercholesterolemia, conditions after acute myocardial infarction and acute cerebrovascular accident, hypertension the dose is 5 mL taken 3-6 times a day. In chronic obstructive pulmonary diseases, interstitial pneumonia, idiopathic pulmonary hypertension, chronic postembolic pulmonary hypertension the dose is 5 mL taken 3-6 times a day. In acute and chronic hepatitis of various etiology, hepatic failure, hepatic encephalopathy due to hyperammoniemia the dose is 5 mL taken 3-6 times a day. In hypoxic states and asthenia, immune correction in impaired thymic function the dose is 5 mL administered 4-8 times a day. The maximum daily dose is 8 g. The duration of treatment course – 8-15 days, the treatment course may be repeated when needed.

Undesirable effects.
Rarely - the feeling of mild discomfort in the stomach and intestine, nausea immediately after drug intake, which resolve spontaneously. Allergic reactions.

Overdose.
Symptoms: hypersensitivity reactions, hypoglycemic states.
Treatment: In case of above symptoms, this medicinal product should be discontinued. Gastric lavage and administration of absorbents should be considered. There is no specific antidote. The treatment is symptomatic.

Pregnancy and lactation.
This medicinal product crosses the placenta and should be administered during pregnancy only in the

case if the expected benefit for mother exceeds the potential risk for fetus. No data are available on the use in nursing mothers.

Pediatric population.
No data are available on the use of this medicinal product in children aged under 18.

Special warnings and precautions for use.
Caution is advised when using this medicinal product in patients with electrolyte disturbances and renal diseases. During treatment, alcohol, nicotine and psychostimulants should be avoided and balanced sleep-wake cycle maintained. In case of treatment-related worsening of asthenia symptoms, this medicinal product should be discontinued.

Effects on ability to drive and use machines.
No effects.

Interaction with other medicinal products and other forms of interaction.
During administration of arginine aspartate, a consideration must be given to the fact that concomitant use of aminophylline and arginine may lead to increased blood insulin levels and co-administration of spironolactone and arginine may result in increased blood potassium levels.

Pharmacological properties.
Pharmacodynamic properties. Tivortin® Aspartate has antihypoxic, antioxidant, detoxication and membrane-stabilizing actions. It plays an essential role in the processes of ammonia neutralization and stimulation of its elimination from the body, and potentiates detoxification function of liver. It exhibits hepatoprotective action and is beneficial to energy supply processes in hepatocytes.
As nitric oxide donor, Tivortin® Aspartate participates in the body energy supply processes, reduces leucocytes and thrombocytes activation and adherence to vascular endothelium, thus preventing the formation and development of atherosclerotic plaques, and has a role in fibrinogenolysis and spermatogenesis.
It exhibits moderate anabolic action, stimulates thymic function, facilitates insulin synthesis and regulates blood glucose levels during exercises, contributes to the adjustment of acid-alkali balance.
Pharmacokinetic properties. Not studied.

Pharmaceutical particulars:
Main physical and chemical properties: transparent, off-white solution with a characteristic caramel odor and sweet taste.

Shelf life.
2 years.

Special precautions for storage.
Store at 15 °C - 25 °C protected from light. Keep out of reach of children. Shelf life after first opening – 14 days.
Do not freeze!

Nature and contents of container.
100 and 200 mL plastic vials. One vial in carton box.

Product category.
OTC product.

Manufacturer.
“Yuria-Pharm”, LLC.
Address. 108 Verbovetskogo St., Cherkasy, 18030, Ukraine, tel. (044) 281-01-01.