Adaptol®

International Non-Proprietary Name (INN): Adaptol

Dosage Form: pills (500 mg)

Structure: 1 pill contains:
Active ingredient: Tetramethyltetraazabicyclooctandionum (mebicarum) 500 mg.
Excipients: methylcellulose, calcium stearate.

Description: Round, flat cylindrical tablets of white or almost white color with a facet and a break line.

Pharmacological classification: tranquilizer (anxiolytic)

ATC code: N05BX

Pharmacological action: anxiolytic, nootropic

Pharmacodynamics:
Chemical structure of Adaptol is similar to natural metabolites of the organism. Its molecule contains two methylated urea fragments, which are part of bicyclic structure. Adaptol has an effect on activity of structures belonging to the limbic-reticular complex in particular on emotiogenic areas of hypothalamus, and has an effect on all the four major neurotransmitter systems: GABA, cholinergic, serotonergic and adrenergic, helping them to balance and to integrate, but it has no peripheral adrenoceptor blocking action.
Adaptol eliminates or reduces anxiety, alarm, fear, internal emotional tension and irritability. The soothing effect is not accompanied by muscle relaxation and loss of coordination. It does not disturb mental and motor performance, so Adaptol can be taken during workday or at school.

Pharmacokinetics:
Absorption: Adaptol is quickly absorbed from the gastro-intestinal tract (77-80%). The maximum concentration of the active ingredient in blood is reached in 0.5 hours after the administration. High concentration of the active ingredient is maintained for 3-4 hours and then gradually decreases.
Distribution: Up to 40% of the dose binds with erythrocytes. The remaining part does not bind with plasma proteins and stays in the blood plasma in a free form, thus the active ingredient is freely distributed throughout the organism and it freely comes through the cell membranes.
Metabolism: The active ingredient is not metabolized and does not accumulate in the body.
Excretion: About 55-70% of the dose is excreted from the body in urine, the rest - in feces in the unchanged form during the day.

Intended uses:
- neuroses and neurosis-like state (irritability, emotional instability, anxiety, fear);
- improvement of tolerability to neuroleptics and tranquilizers in order to eliminate somatic-vegetative and neurological side effects caused by them;
- cardialgia of various nature (if not caused by coronary heart disease);
- nicotine abstinence (as part of the complex therapy to reduce the tobacco addiction);
- mitigation of somatic-vegetative symptoms of premenstrual syndrome and menopause.

**Contraindications:**
Hypersensitivity to ingredients of the drug, age below 18 years old, pregnancy and lactation.

**Dosage and administration:**
Ingest by mouth without regard to timing of food: 500 mg 2-3 times a day. The maximum single dosage is 3 g; the maximum daily dosage is 10 g. The length of the treatment varies from several days to 2-3 months.
In the complex treatment of nicotine dependence it is recommended to take 500-1000 mg 3 times a day for 5-6 weeks.
If you missed taking the drug, the treatment dosage should continue to be the same.

**Side effects (rare):**
Dizziness, decrease of arterial pressure, dyspeptic disorders, allergic reactions (skin rashes, itching).
(At high doses) bronchial spasm, declination of body temperature, weakness. Decrease of arterial pressure or body temperature do not require cessation of treatment. Blood pressure and body temperature return to normal on their own. In case of allergic reactions administration of the drug should be discontinued.

**Overdose:**
The toxicity of Adaptol is very low. If the dosage is significantly exceeded, the following symptoms may arise: weakness, arterial hypotension and dizziness. In this case it is necessary to conduct conventional treatment for detoxification including gastric lavage.

**Interaction with other drugs:**
Adaptol can be combined with antipsychotics, tranquilizers (including benzodiazepines), opiates, antidepressants and psychostimulants.

**Pregnancy and lactation:**
Adaptol penetrates well into all tissues and fluids. There is not enough clinical study on the use of the drug during pregnancy and lactation (breast-feeding). Therefore it is not recommended to prescribe the drug to this category of patients.

**Influence on the ability to drive vehicles and operate mechanisms:**
The drug can cause the decrease of arterial pressure and weakness, which can adversely affect the ability to drive vehicles and operate mechanisms. Special caution should be taken.

**Terms of release from pharmacy:** on prescription

**Storage conditions:** store in a dry place at temperatures no higher than 25°C. Keep out of reach of children.

**Shelf life:** 4 years. Do not use beyond the expiration date.

**Country of manufacture:** Latvia