

# Afobazole® instructions

translated from original Russian instructions by Extrapharmacy Online Store

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**Name in Cyrillic :** АФОБАЗОЛ

**Active substance :** Fabomotisol (in the form of dihydrochloride)

## **Pharmacologic action :**

Afobazole is a selective non-benzodiazepine anxiolytic. Afobazole acts on sigma-1 receptors in nerve cells of the brain, stabilizes GABA / benzodiazepine receptors and restores their sensitivity to endogenous mediators of inhibition. Afobazole also increases the bioenergetic potential of neurons and has a neuroprotective effect: restores and protects nerve cells.

The effect of Afobazole is realized mainly in the form of a combination of anxiolytic (anti-anxiety) and light stimulating (activating) effects. Afobazole reduces or eliminates feelings of anxiety (anxiety, bad forebodings, fears), irritability, tension (fearfulness, tearfulness, anxiety, inability to relax, insomnia, fear), depressive mood, somatic manifestations of anxiety (muscle, sensory, cardiovascular, respiratory, gastrointestinal symptoms), vegetative disorders (dry mouth, sweating, dizziness), cognitive disorders (difficulty concentrating, weakened memory), incl. arising from stress disorders (adaptation disorders). The use of the drug is particularly indicated in people with mostly asthenic personality traits in the form of anxious suspicion, uncertainty, increased vulnerability and emotional lability, a tendency to emotional-stressful reactions.

The effect of the drug develops on the 5th-7th day of treatment. The maximum effect is achieved by the end of 4 weeks of treatment and remains after the end of treatment on average 1-2 weeks.

Afobazole does not cause muscle weakness, drowsiness and does not have a negative effect on concentration and memory. Afobazole is not addictive.

## **Pharmacokinetics :**

After oral administration Afobazole is absorbed well and quickly from the digestive tract.

$C_{max}$  -  $0.130 \pm 0.073$  mcg / ml;  $T_{max}$  -  $0.85 \pm 0.13$  h.

Afobazole undergoes the "first pass" effect through the liver, the main ways of metabolism are hydroxylation on the aromatic ring of the benzimidazole ring and oxidation by the morpholino fragment. Afobazole is intensively distributed over well-vascularized organs, it is characterized by rapid transfer from the central pool (blood plasma) to the peripheral (highly vascularized organs and tissues).

$T_{1/2}$  of fabomotizol is  $0.82 \pm 0.54$  h. Short  $T_{1/2}$  is caused by intensive biotransformation of the drug and rapid distribution from the blood plasma to the organs and tissues. The drug is excreted mainly in the form of metabolites and partially unchanged in urine and feces.

With prolonged use, it does not accumulate in the body.

## **Indications :**

- generalized anxiety disorders;
- neurasthenia;
- Adaptation disorders.

In patients with various physical diseases:

- bronchial asthma;
- irritable bowel syndrome;
- systemic lupus erythematosus;

- ischemic heart disease ;
- hypertonic disease;
- arrhythmia;
- dermatological, oncological and other diseases.

In the treatment of :

- sleep disorders associated with anxiety;
- neurocirculatory dystonia;
- premenstrual syndrome;
- alcohol abstinence syndrome;
- to facilitate the syndrome of "cancellation" when quitting smoking.

**Contraindications :**

- hypersensitivity to the components of the drug;
- galactose intolerance, lactase deficiency or glucose-galactose malabsorption;
- pregnancy;
- lactation period (breastfeeding);
- children under 18 years.

**Side effects :**

Possible: allergic reactions.

Rarely: headache, which usually passes by itself and does not require drug withdrawal.

**Interaction :**

Afobazole does not interact with ethanol and does not affect the hypnotic effect of thiopental.

Enhances the anticonvulsant effect of carbamazepine.

It causes an increase in the anxiolytic effect of diazepam.

**Dosing and Administration**

Afobazole should be taken after eating.

Optimal single doses - 10 mg; per day - 30 mg, divided into 3 doses during the day,

Duration of the course is 2-4 weeks.

If necessary, on the recommendation of a doctor, the daily dose of Afobazole can be increased to 60 mg, and the duration of treatment up to 3 months.

**Overdose**

Symptoms: with a significant overdose and intoxication it is possible to develop a sedative effect and increased drowsiness without manifestations of muscle relaxation.

Treatment: as an emergency - caffeine 20% solution in ampoules of 1.0 ml 2-3 times per day.

**Special instructions**

The drug does not adversely affect the driving of motor vehicles and the performance of potentially hazardous activities requiring increased concentration of attention and speed of psychomotor reactions.

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**Storage :** The temperature is not above 25 ° C. Keep out of the reach of children. Shelf-life of the drug is 3 years.