

# Phenazepam®

translated from original Russian leaflet by RussianMeds Online Pharmacy

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**Name in Cyrillic:** Феназепам

**Active substance:** Bromdihydrochlorphenylbenzodiazepine

**Pharmacologic effect:** sedative, hypnotic, muscle relaxant, anxiolytic, anticonvulsant

## Pharmacodynamics:

Phenazepam is anxiolytic (tranquilizer) benzodiazepine. It has anxiolytic, sedative-hypnotic, anticonvulsant and central muscle relaxant effect.

Phenazepam increases the inhibitory effect of GABA in the transmission of nerve impulses. Phenazepam stimulates benzodiazepine receptors located in the allosteric center of postsynaptic GABA receptors ascending activating reticular formation of the brain stem; reduces the excitability of the subcortical structures of the brain (the limbic system, thalamus, hypothalamus), inhibits polysynaptic spinal reflexes.

The anxiolytic effect is due to the influence on the amygdala of the limbic system and manifests itself in the reduction of emotional stress, easing anxiety, fear, anxiety.

Sedation due to the influence on the reticular formation of the brain stem and the nonspecific thalamic nuclei and manifested a decrease in symptoms of neurotic origin.

Phenazepam has practically no effect on the productive psychotic symptoms genesis (acute delusional, hallucinatory, affective disorders), it is rarely observed decrease in affective intensity, delusional disorders.

Hypnotic effects associated with inhibition of the cells of the reticular formation of the brain. Reduces effects of emotional, autonomic and motor stimuli that disturb sleep.

Anticonvulsant action is realized by increasing presynaptic inhibition suppresses the spread of seizure pulse, but does not eliminate the excited state of the hearth.

Central muscle relaxant effect is due to inhibition of polysynaptic spinal afferent inhibitory ways (to a lesser extent - and monosynaptic). Perhaps, and direct inhibition of motor nerve and muscle function.

## Pharmacokinetics:

After oral administration, Phenazepam is well absorbed from the gastrointestinal tract, T<sub>max</sub> in plasma : 1-2 hours

Phenazepam is metabolized in the liver. T<sub>1/2</sub> : 6-10-18 hours

Phenazepam is excreted mainly by the kidneys

## Indications:

neurotic, neurosis, psychotic, psychopathic and other conditions accompanied by anxiety, fear, increased irritability, tension, and emotional lability;

reactive psychosis and hypochondriacal-senestopatchesky syndrome (including resistant to the action of other tranquilizers);

autonomic dysfunction and sleep disorders;

prophylaxis of conditions of fear and emotional stress;

temporal and myoclonic epilepsy (as an anticonvulsant);

treatment of hyperkinesis and tics, muscle rigidity, autonomic lability.

## Contraindications:

hypersensitivity (including other benzodiazepines);

coma, shock;

myasthenia gravis;

angle-closure glaucoma (acute onset or predisposition);

acute poisoning by alcohol (with the weakening of vital functions), narcotic analgesics and hypnotics;

Severe COPD (possibly increasing respiratory failure);  
acute respiratory failure;  
severe depression (suicidal tendencies may emerge);  
pregnancy (I term); lactation;  
childhood and adolescence to 18 years (the safety and effectiveness are not determined).

### **Pregnancy and breast-feeding:**

In pregnancy the use is possible only for health reasons. It has a toxic effect on the fetus and increases the incidence of birth defects when used in the I trimester of pregnancy. Reception at therapeutic doses in later stages of pregnancy can cause CNS depression in the neonate. The constant use during pregnancy may lead to physical dependence with the development of withdrawal symptoms in the newborn. Children (especially at a younger age) are very sensitive to the depressant action of benzodiazepines.

Application just before birth or during parturition may cause neonatal respiratory depression, decreased muscle tone, hypotension, hypothermia and a weak act of sucking (flaccid baby syndrome).

### **Side effects:**

*From the central and peripheral nervous system:* at the beginning of treatment (particularly in elderly patients) - drowsiness, fatigue, dizziness, decreased ability to concentrate, ataxia, disorientation, unsteady gait, slowing of mental and motor reactions, confusion; rarely - headache, euphoria, depression, tremors, loss of memory, impaired motor coordination (particularly at high doses), depressed mood, dystonic extrapyramidal reactions (uncontrolled movements, including the eyes), fatigue, muscle weakness, dysarthria, epileptic seizures (epilepsy patients); very rarely - paradoxical reaction (aggressive outbursts, agitation, anxiety, suicidal tendencies, muscle spasms, hallucinations, agitation, irritability, anxiety, insomnia).

*From the side of hematopoiesis:* leukopenia, neutropenia, agranulocytosis (chills, pyrexia, sore throat, extreme tiredness or weakness), anemia, thrombocytopenia.

*From the digestive system:* dry mouth or salivation, heartburn, nausea, vomiting, loss of appetite, constipation or diarrhea; abnormal liver function, increased activity of hepatic transaminases and alkaline phosphatase, jaundice.

*From the urogenital system:* urinary incontinence, urinary retention, renal dysfunction, decreased or increased libido, dysmenorrhea.

*Allergic reactions:* skin rash, pruritus.

*Other:* addiction, drug dependency, lowering blood pressure; rarely - blurred vision (diplopia), weight loss, tachycardia. With a sharp decrease in dose or discontinuation - withdrawal symptoms (irritability, nervousness, sleep disturbances, dysphoria, a spasm of smooth muscles of internal organs and skeletal muscles, depersonalization, increased sweating, depression, nausea, vomiting, tremor, perception disorders, including hyperacusis, paresthesia, photophobia, tachycardia, seizures, rare - acute psychosis).

### **Interaction:**

Phenazepam reduces the effectiveness of levodopa in patients with Parkinson's disease.

Phenazepam may increase the toxicity of zidovudine.

There is a mutual enhancement effect with antipsychotic, antiepileptic, or hypnotic drugs, as well as central muscle relaxants, narcotic analgesics, ethanol.

Inhibitors of microsomal oxidation increase the risk of toxic effects. Inductors microsomal liver enzymes decrease the efficiency.

Increasing the concentration of imipramine in blood serum.

In an application with antihypertensive drugs may increase antihypertensive action.

If simultaneous appointment of clozapine Phenazepam may increase the respiratory depression.

### **Dosing and Administration:**

For sleep disorders, take 0.5mg 20-30 minutes before bedtime.

For the treatment of neurotic, psychopathic, and psychopathy-like conditions the initial dose is 0.5-1 mg 2-3 times a day. After 2-4 days in view of efficacy and tolerability, the dose can be increased to 4-6 mg per day.

In severe agitation, fear, anxiety, treatment is initiated with a dose of 3 mg / day, quickly increasing the dose to produce a therapeutic effect.

In the treatment of epilepsy : 2-10 mg / day.

For the treatment of alcohol withdrawal : 2-5 mg / day.

The average daily dose is 1.5-5 mg, it is separated into 2-3 doses, usually 0.5-1 mg in the morning and afternoon, and 2.5 mg at night. In neurological practice for diseases with muscle hypertonicity appoint 2-3 mg 1-2 times a day.

The maximum daily dose - 10 mg.

In order to avoid the development of drug dependence at course treatment duration of Phenazepam application is 2 weeks (in some cases the duration of treatment can be increased up to 2 months). If you cancel Phenazepam - reduce the dose gradually.

#### **Overdose:**

Symptoms: marked depression of consciousness, cardiac and respiratory activity, severe drowsiness, prolonged confusion, decreased reflexes, prolonged dysarthria, nystagmus, tremor, bradycardia, dyspnea or shortness of breath, decreased blood pressure, coma.

Treatment: gastric lavage, the appointment of activated carbon, the control of vital functions, maintaining respiratory and cardiovascular activity, symptomatic therapy. Hemodialysis is ineffective.

Specific antagonist - flumazenil (in a hospital) / in 0.2 mg if necessary - up to 1 mg of 5% glucose solution or 0.9% sodium chloride solution.

#### **Special instructions:**

In renal and / or hepatic failure and long-term treatment is necessary to control the picture of peripheral blood and liver enzymes.

In patients not previously treated with psychoactive drugs, therapeutic response is observed in the application of Phenazepam at lower doses, compared with patients taking antidepressants, anxiolytics or suffering from alcoholism.

Like other benzodiazepines Phenazepam can be addictive after long administration in large doses (up to 4 mg / day). In a sudden discontinuation may experience withdrawal symptoms (including depression, irritability, insomnia, increased sweating), especially after long-term use (8-12 weeks). If the patient has such unusual reactions, as increased aggressiveness, acute state of excitement, anxiety, suicidal thoughts, hallucinations, increased muscle cramps, difficulty falling asleep, sleep surface, treatment should be discontinued.

In the treatment the use of ethanol is strictly prohibited.

The efficacy and safety of the drug in patients younger than 18 years have not been established.

During the period of treatment must be careful when driving and occupation of other potentially hazardous activities that require high concentration and psychomotor speed reactions.

**Manufacturer:** Valenta-Pharm (Russia)

#### **Reliable supplier with fast Worldwide shipping:**

RussianMeds Online Pharmacy

<https://russianmeds.com>

#### **Storage:**

The temperature is not above 25 °C (77 °F)