

Baclosan® (Baclofen)

translated from original Russian leaflet by RussianMeds Store

<https://russianmeds.com>

Name in Cyrillic: Баклосан®

Active substance: Baclofen

Pharmacologic effect: Centrally acting muscle relaxant

Pharmacodynamics:

Baclofen is a muscle relaxant of central action, GABAB receptor agonist. By reducing the excitability of the terminal sections of afferent sensory fibers and suppressing intermediate neurons, Baclofen inhibits mono- and polysynaptic transmission of nerve impulses; reduces prestressing of the muscle spindles. Baclofen does not affect the transmission of impulses in neuromuscular synapses. In neurological diseases accompanied by spasticity of skeletal muscles, it relieves painful spasms and clonic convulsions. Baclofen increases the range of motion in the joints, facilitates passive and active kinesitherapy (physical exercises, massage, manual therapy).

Pharmacokinetics:

Absorption is high. Cmax in plasma is achieved 2-3 hours after taking the drug.

Plasma protein binding is about 30%. Baclofen crosses the placental barrier and is excreted in breast milk.

Baclofen is metabolized in the liver, and excreted in the urine, mainly unchanged.

Indications:

Muscle spasticity in:

- multiple sclerosis;
- diseases of the spinal cord (tumors, syringomyelia, motor neuron diseases, injuries, myelitis);
- cerebrovascular diseases;
- cerebral palsy;
- meningitis;
- craniocerebral injuries.

Contraindications:

- psychoses;
- Parkinson's disease;
- epilepsy;
- convulsions (including history);
- peptic ulcer of the stomach and duodenum;
- lactase deficiency, lactose intolerance, glucose-galactose malabsorption;
- pregnancy;
- lactation (breastfeeding);
- hypersensitivity to baclofen.

Use with caution:

Use with caution for cerebrovascular insufficiency, cerebral atherosclerosis, chronic renal failure, in elderly patients, in children under 3 years of age.

Pregnancy and breast-feeding:

Baclofen is contraindicated for use during pregnancy and lactation (breastfeeding).

Side effects:

very rare - less than 0.01% ; rare - more than 0.01% and less than 0.1%; infrequent - more than 0.1% and less than 1%,; frequent - more than 1% and less than 10%; very frequent - more than 10%.

Nervous system:

very frequent - drowsiness, sedation;

frequent - dizziness, weakness, fatigue, confusion, gait disturbance, insomnia, euphoria, depression, asthenia, ataxia, tremor, hallucinations, nightmares, nystagmus, dry mouth;

rare - paresthesia, dysarthria.

Cardiovascular system:

frequent - a decrease in cardiac output, arterial hypotension.

Gastrointestinal tract:

very frequent - nausea;

frequent - vomiting, constipation, diarrhea, dyspeptic symptoms;

rare - abdominal pain, dysgeusia, impaired liver function.

Respiratory system:

frequent - respiratory depression.

Musculoskeletal system:

frequent - myalgia.

Senses:

frequent - paresis of accommodation, visual disturbances.

Skin and subcutaneous tissue:

frequent - hyperhidrosis, rash.

Kidneys and urinary system:

frequent - polyuria, enuresis, dysuria;

rare - urinary retention.

Reproductive system:

rare - erectile dysfunction.

General disorders:

very rare - hypothermia.

In isolated cases, an increase in spasticity was observed, which was regarded as a paradoxical reaction to the drug.

Interaction:

With the simultaneous use, Baclofen enhances the effect of drugs that affect the central nervous system, antihypertensive, anti-gout drugs, ethanol.

With the simultaneous use of Baclofen with tricyclic antidepressants, a significant decrease in muscle tone is possible.

While taking Baclofen with levodopa and carbidopa, hallucinations, confusion of consciousness, agitation may occur.

Dosing and Administration:

Baclofen is taken orally, during meals. If you miss the next dose, you should not take a double dose of the drug.

Adults :

The initial dose is 5 mg 3 times / day, followed by an increase in dose every 3 days by 5 mg until the onset of a therapeutic effect (usually up to 30-75 mg / day). The maximum daily dose is 100 mg.

The final dose is set in such a way that the decrease in muscle tone does not lead to excessive myasthenia gravis and does not impair motor functions. With hypersensitivity, the initial daily dose is 5-10 mg, followed by a slower increase.

In chronic renal failure and during hemodialysis, the daily dose is 5 mg.

In patients requiring high doses of baclofen (from 75 mg to 100 mg per day), the drug should be used in tablets of 25 mg.

In patients over 65 years of age, the dose of the drug should be increased with caution, due to an increased risk of side effects.

Children:

The initial dose is 5 mg 3 times / day. If necessary, the dose can be cautiously increased every 3 days by 5 mg until the onset of a therapeutic effect.

The following doses are usually recommended: in children from 3 to 6 years old - 20-30 mg / day, from 6 to 10 years old - 30-60 mg / day, in children over 10 years old the maximum daily dose is 2.5 mg / kg of body weight; initial dose - 1.5-2 mg/kg of body weight.

Cancellation of the drug is carried out gradually (within 1-2 weeks).

Overdose:

Symptoms: muscle hypotension, depression of the respiratory center, confusion of consciousness, coma (after the return of consciousness, muscle hypotension may persist for 72 hours).

Treatment: drinking plenty of water, taking diuretics, with respiratory depression - mechanical ventilation. There is no specific antidote.

Special instructions:

Side effects are often transient in nature, they should be distinguished from the symptoms of the disease for which treatment is being carried out: with concomitant epilepsy, treatment is carried out without discontinuation of antiepileptic drugs.

In patients with liver disease and diabetes, it is necessary to periodically monitor the activity of hepatic transaminases and alkaline phosphatase, as well as blood glucose levels.

Patients taking Baclofen should refrain from potentially hazardous activities associated with the need for increased attention and rapid psychomotor reactions.

Manufacturer: Polpharma (Poland)

Reliable supplier with fast Worldwide shipping:

RussianMeds Online Store

<https://russianmeds.com>

Storage:

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

Keep out of the reach of children.