Actovegin® tablets

Registration number:
P N014635/03 [П N014635/03]

Trade name:
Actovegin®

International non-proprietary name (INN):
Deproteinized Calf Blood Hemoderivative

Dosage form:
Coated Tablets

Composition per tablet:
1 coated tablet contains:

Core:
Active ingredient: Deproteinized calf blood hemoderivative – 200.0 mg (in the form of Actovegin® granulate – 345.0 mg)

Excipients: Magnesium stearate – 2.0 mg, Talc – 3.0 mg

Coating:
Acacia gum – 6.8 mg, Mountain wax (glycol) – 0.1 mg, Hypromellose phthalate – 29.45 mg, Diethyl phthalate – 11.8 mg, Quinoline yellow aluminum lake dye – 2.0 mg, Macrogol-6000 – 2.95 mg, Povidone K30 – 1.54 mg, Sucrose – 52.3 mg, Talc – 42.2 mg, Titanium dioxide – 0.86 mg

Description:
Round, biconvex coated tablets, greenish-yellow in color, glossy.

Pharmacotherapeutic group:
Tissue Regeneration Stimulator

ATC code:
[B06AB]

Pharmacological properties:

Pharmacodynamics:
Actovegin® is an antihypoxant that exhibits three types of effects: metabolic, neuroprotective, and microcirculatory. It enhances oxygen uptake and utilization. The inositol phospho-oligosaccharides included in the preparation positively influence glucose transport and utilization, improving cellular energy metabolism and reducing lactate formation under ischemic conditions.

Actovegin® prevents apoptosis induced by beta-amyloid peptide (Aβ25-35) and modulates nuclear factor kappa B (NF-κB) activity, which plays a key role in apoptosis and inflammation regulation in the central and peripheral nervous systems. Additionally, it inhibits poly(ADP-ribose) polymerase (PARP), which is significant for DNA repair but may lead to cell death under excessive activation during cerebrovascular diseases and diabetic polyneuropathy.

Positive microcirculatory effects include increased capillary blood flow, reduced pericapillary zone, lowered myogenic tone of precapillary arterioles and capillary sphincters, reduced arterio-venular shunt flow, and stimulation of endothelial nitric oxide synthase function. Effects occur within 30 minutes of administration, with maximum efficacy at 2-6 hours.

Pharmacokinetics:
Pharmacokinetic parameters cannot be studied as Actovegin® consists solely of physiological components naturally present in the body.

Indications:
As part of complex therapy:

- Symptomatic treatment of cognitive impairment, including post-stroke cognitive dysfunction and dementia
- Symptomatic treatment of peripheral circulation disorders and their consequences
- Symptomatic treatment of diabetic polyneuropathy (DPN)

Contraindications:

- Hypersensitivity to Actovegin® or its components
- Fructose intolerance, glucose-galactose malabsorption, or sucrose-isomaltase deficiency
- Children under 18 years

Use with caution:

During pregnancy and lactation.

Pregnancy and lactation:

Actovegin® should only be used when therapeutic benefits outweigh potential risks to the fetus or child.

Dosage and administration:

Oral use, without chewing, before meals with a small amount of liquid.

Post-stroke cognitive impairment:
Acute ischemic stroke: Starting from days 5-7, administer 2000 mg/day intravenously for up to 20 infusions, followed by 2 tablets three times daily (1200 mg/day) for 6 months.

Dementia:
2 tablets three times daily (1200 mg/day) for 20 weeks.

Peripheral circulation disorders and their consequences:
1-2 tablets three times daily (600-1200 mg/day) for 4-6 weeks.

Diabetic polyneuropathy:
2000 mg/day intravenously for 20 infusions, followed by 3 tablets three times daily (1800 mg/day) for 4-5 months.

Side effects:

Frequency classification: Very common (≥1/10); Common (≥1/100 to <1/10); Uncommon (≥1/1000 to <1/100); Rare (≥1/10000 to <1/1000); Very rare (<1/10000); Unknown (cannot be estimated from available data).

Immune system disorders:
Rare: Allergic reactions (drug fever, shock symptoms).

Skin and subcutaneous tissue disorders:
Rare: Urticaria, flushing.

Overdose:

Preclinical studies show Actovegin® has no toxic effects even at doses 30-40 times higher than those recommended for human use. No overdose cases have been reported.

Drug interactions:

Currently unknown.

Special instructions:

Clinical Data: In the ARTEMIDA study (NCT01582854), investigating Actovegin®'s effects on cognitive impairment post-ischemic stroke, serious adverse event rates and mortality were similar in treatment and placebo groups. While recurrent ischemic strokes were observed more frequently in the Actovegin® group, the difference was not statistically significant, and no causal relationship was established.

Use in Pediatric Patients: Data on Actovegin® use in children are unavailable; hence, its use in this population is not recommended.

Effects on Driving and Machine Operation: No effects established.

Form of release:
200 mg coated tablets.

50 tablets in amber glass bottles with screw caps, packed in cardboard boxes with security stickers.

Storage conditions:
Store in a dark place at a temperature not exceeding 25°C. Keep out of reach of children.

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

Dispensing conditions:
Prescription only.

Manufacturer:
Takeda GmbH, Germany Lehnitzstrasse 70-98, 16515 Oranienburg, Germany

These instructions translated from official manufacturer instructions in Russian by Extrapharma online pharmacy