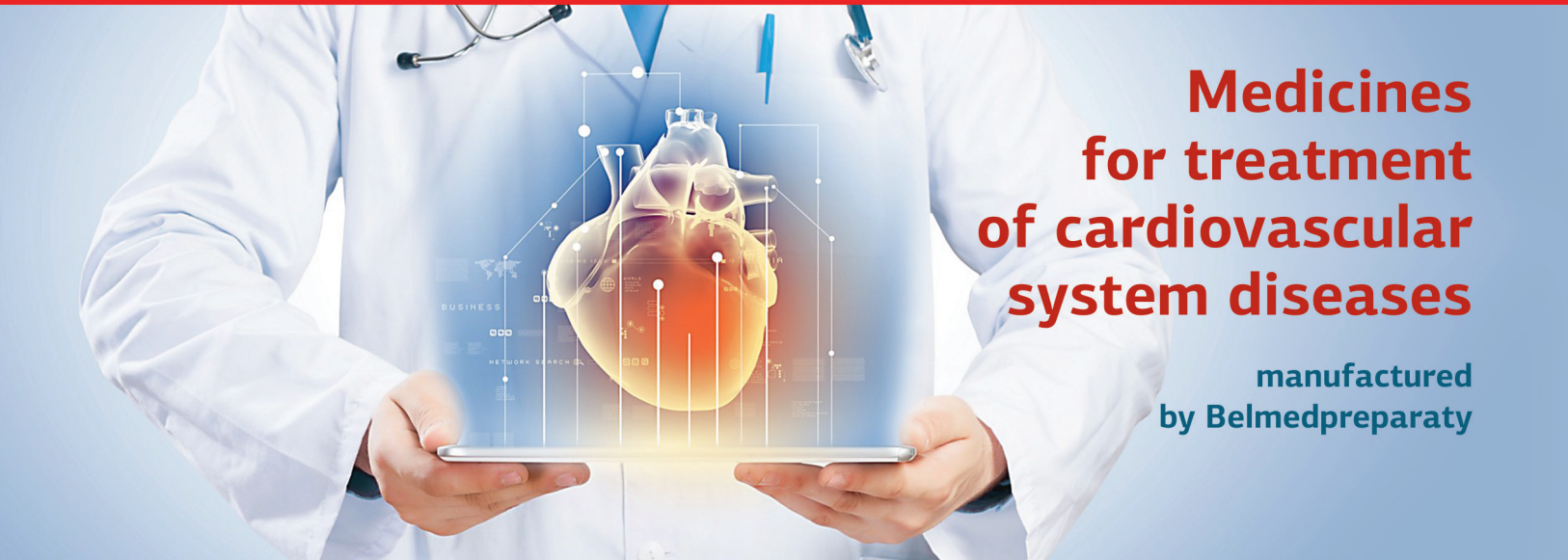
Belmedpreparaty



Medicines for treatment of cardiovascular system diseases

manufactured by Belmedpreparaty

Mildrocard

capsules 250 mg

International non-proprietary name: Meldonium.
Description: white hard gelatine capsules, number 1.
Composition: each capsule contains:
active substance: meldonium – 250 mg;
excipients: calcium stearate, potato starch.
Hard gelatin capsule composition: gelatin, glycerin, purified water, titanium dioxide, sodium laurylsulphate.
Pharmacotherapeutic group: Tonics.
ATC code: A13A.

Therapeutic indications
In the combination therapy in the following cases:

- during physical and psycho-emotional stress accompanied by decreased performance;
- during the recovery period after previous cerebrovascular diseases, traumatic brain injury and encephalitis (according to the doctor's recommendations).

Mode of administration and doses
Administer orally. The daily dose for adults is 500 mg (2 capsules). The entire dose can be taken in the morning once or divided into 2 doses (1 capsule). Due to a possible stimulating effect, it is recommended to administer the drug product in the morning.
Duration of the therapy course should be determined by the doctor.
If you missed the next dose, take it immediately. Do not take a double dose to make up for a missed one. Continue administration according to the doctor's recommendations.

Mildrocard

solution for intravenous and intramuscular injection 100 mg/ml

International non-proprietary name: Meldonium.

Description: clear, colorless solution.

Composition: each ampoule contains:
active substance: meldonium – 500 mg;
excipients: water for injection.

Pharmacotherapeutic group: Other cardiac preparations.

ATC code: C01EB.

Therapeutic indications

Mildrocard is used in the combination therapy in the following cases:

- cardiovascular diseases – stable angina, chronic heart failure (NYHA I-III functional class), ischemic cardiomyopathy, recovery period after myocardial infarction;
- acute and chronic ischemic cerebrovascular disorders, recovery period after cerebrovascular diseases, head injuries.

Mode of administration and doses

Due to a possible stimulating effect, it is recommended to administer the drug product in the morning hours.

Cardiovascular diseases (in the combination therapy): intravenously 0.5-1.0 g per day, then switch to administrating the oral dosage form (orally 250 mg, 500-1,000 mg per day). The course of treatment is 4-6 weeks.

Acute and chronic ischemic cerebrovascular disorders: intravenously 500 mg once per day for 2-3 weeks. Treatment is continued with the oral dosage form (250 mg) with administration of 500 mg per day. The average duration of treatment is 6 weeks.

Riboxin

film-coated tablets 200 mg

International non-proprietary name: Inosine.

Description: pale yellow to peach, biconvex, film-coated tablets.

Composition: each tablet contains:

active substance: inosine – 200 mg;

excipients: methylcellulose, calcium stearate, sugar, potato starch, opadry II yellow (polyvinyl alcohol, titanium dioxide, talc, polyethyleneglycol, ferric oxide, pigment – aluminum lake on the basis of quinoline yellow E104).

Pharmacotherapeutic group: Metabolic agent.

ATC code: C01EB.

Therapeutic indications

As a part of the complex therapy for various diseases:

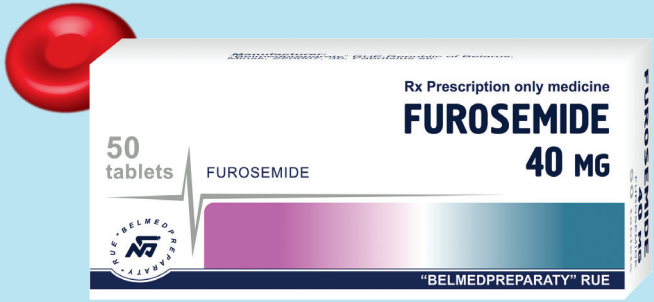
- ischemic heart disease (myocardial infarction, coronary failure, cardiac rhythm disturbance);
- cardiomyopathy of various genesis, congenital and acquired heart diseases, rheumatic heart diseases, myocarditis, coronary atherosclerosis, pulmonary heart (right heart enlargement and expansion), dystrophic changes in the myocardium after hard physical exercises and previous infectious diseases or as a result of endocrine disorders;
- hepatic cirrhosis, acute and chronic hepatitis, alcohol- and drug product-induced liver injuries, fatty degeneration of liver, gastric and duodenal ulcer. Drug product poisoning; surgery on an isolated kidney (as a pharmacological protection drug product, when the blood circulation of an organ under operation is terminated temporarily).

Mode of administration and doses

The daily oral dose is 600-2400 mg. On the first days of treatment the daily dose is 600-800 mg (200 mg 3-4 times a day). In case of good tolerance the daily dose is increased (on the 2nd-3rd day) up to 1200 mg, if necessary – up to 2400 mg/day. The treatment course is 4 weeks to 1.5-3 months.

Furosemide

tablets 40 mg



International non-proprietary name: Furosemide.

Description: white to off-white, flat-faced, beveled edge tablets.

Composition: each tablet contains:

active substance: furosemide – 40 mg;

excipients: lactose monohydrate, magnesium stearate, potato starch.

Pharmacotherapeutic group: High-ceiling diuretics. Sulfonamides.

ATC code: C03CA01.

Therapeutic indications

Edema of cardiac or renal origin. Edema of hepatic origin, usually in combination with potassium-sparing diuretics. Arterial hypertension in patients with chronic renal failure who are contraindicated for thiazide diuretics (especially when creatinine clearance is less than 30 ml/min).

Mode of administration and doses

The medicinal product is administered before meals. Dosage depends on the course and severity of the disease.

Adults. In edema of cardiac, renal or hepatic origin:

- moderate state: 1/2-1 tablet a day;
- severe state: 2-3 tablets a day in 1 or 2 administrations, or 3-4 tablets a day in 2 administrations.

Children. For treatment of edema, the daily dose is 1-2 mg/kg of body weight in 1-2 administrations.

Moxonidine

coated tablets 0.2 mg; 0.3 mg; 0.4 mg

International non-proprietary name: Moxonidine
Description: white or off-white, round, biconvex coated tablets (0.2 mg).
Pink, round, biconvex coated tablets (0.3 mg).
Orange to red-orange, round, biconvex coated tablets (0.4 mg).
Composition: each tablet contains:
active substance: moxonidine – 0.2 mg; 0.3 mg; 0.4 mg;
excipients: lactose monohydrate; povidone K-25; crospovidone, magnesium stearate.
Pharmacotherapeutic group: Antihypertensives. Imidazoline receptor agonists.
ATC code: C02AC05.
Therapeutic indications
Hypertension.

Mode of administration and doses
Orally regardless of food intake, with plenty of liquid. *Adults* (including elderly patients with normal renal function): treatment should start with 0.2 mg of moxonidine per day once, preferably in the morning. In case of the insufficient therapeutic effect after 3 weeks of treatment the dose may be increased to 0.4 mg per day once or may be divided into 2 doses (morning and evening).
If after another 3 weeks of treatment the therapeutic effect is still not reached, the dose may be increased to a maximum of 0.6 mg divided into 2 doses (morning and evening).
The maximum single dose is 0.4 mg of moxonidine and the maximum daily dose is 0.6 mg (divided into 2 doses, morning and evening). Do not exceed the recommended dose.
Sudden discontinuation of moxonidine is not recommended. Moxonidine should be discontinued gradually during 2 weeks.

Betaxolol

tablets 20 mg

International non-proprietary name: Betaxolol.

Description: white or off-white, round, biconvex coated tablets.

Composition: each tablet contains:

active substance: betaxolol hydrochloride – 20 mg;

excipients: lactose monohydrate, sodium starch glycolate (type A), silica dioxide colloidal anhydrous, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, titanium dioxide (E 171), talc, macrogol/PEG 3350, lecithin (soya).

Pharmacotherapeutic group: Selective β-blocker agent.

ATC code: C07AB05.

Therapeutic indications

- arterial hypertension;
- prevention of angina attacks.

Mode of administration and doses

The drug product should be administered orally, without chewing, with plenty of liquid. Starting dose is 1 tablet (20 mg) per day.

Amlodipine

tablets 5 mg

International non-proprietary name: Amlodipine.

Description: white or off-white flat-faced round beveled tablets.

Composition: each tablet contains:

active substance: amlodipine (as amlodipine besilate) – 5 mg;

excipients: microcrystalline cellulose, potato starch, calcium stearate, lactose monohydrate.

Pharmacotherapeutic group: Calcium channel blocking agents. Calcium channel selective blocking agents with a primary effect on vessels.

ATC code: C08CA01.

Therapeutic indications

Arterial hypertension (monotherapy or in combination with other hypotensive drug products), stable effort and vasospastic angina (monotherapy or in combination with other hypotensive drug products).

Mode of administration and doses

Orally as a single dose. Initial dose in arterial hypertension and angina is 5 mg daily which, if required, may be increased up to the maximum dose – 10 mg daily. Patients with low body weight or height as well as with pronounced liver failure may require lower doses.

In patients with arterial hypertension, amlodipine is used in combination with thiazide diuretics, alpha and beta blocking agents or ACE inhibitors.

In angina, amlodipine may be used as monotherapy or in combination with other drug products for angina in patients with no effect from nitrates and/or adequate dose of beta blocking agents.

In concomitant treatment with thiazide diuretics, beta blocking agents or ACE inhibitors, amlodipine dose adjustment is required.

Losartan

film-coated tablets 50 mg, 100 mg

International non-proprietary name: Losartan.

Description: white to off white, round, biconvex, film-coated tablets.

The break line is only to facilitate breaking for ease of swallowing and not to divide into equal doses. The film coating on the tablet surface may be uneven.

Composition: each film-coated tablet contains:

active substance: losartan potassium – 50 mg or 100 mg;

excipients: pregelatinized starch, croscarmellose sodium, colloidal anhydrous silica, calcium stearate (E572), microcrystalline cellulose (E460) Opadry II White (85F).

Opadry II White (85F) per 1 tablet: polyvinyl alcohol, partially hydrolyzed, macrogol / polyethylene glycol 3350, talc (E553); titanium dioxide (E171).

Pharmacotherapeutic group: Drugs affecting the renin-angiotensin system. Angiotensin II antagonists.

ATC code: C09CA01.

Therapeutic indications

- Treatment of essential hypertension.
- Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus with proteinuria ≥0.5 g/day as part of an antihypertensive treatment.
- Reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy documented by ECG.

Mode of administration and doses

Losartan tablets should be swallowed with a glass of water. Losartan tablets may be administered with or without food.

Hypertension: the usual starting and maintenance dose is 50 mg once daily for most patients. The maximal

antihypertensive effect is attained 3-6 weeks after initiation of therapy. Some patients may receive an additional benefit by increasing the dose to 100 mg once daily (in the morning).

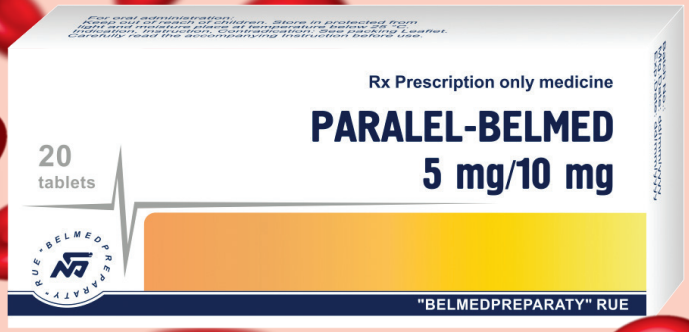
Losartan tablets may be administered with other antihypertensive agents, especially with diuretics, e.g. hydrochlorothiazide.

Hypertensive type II diabetic patients with proteinuria ≥ 0.5 g/day: the usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily based on blood pressure response from one month onwards after initiation of therapy. May be administered with other antihypertensive agents (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used hypoglycemic agents (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

Reduction in the risk of stroke in hypertensive patients with left ventricular hypertrophy documented by ECG: the usual starting dose is 50 mg of Losartan tablet once daily. A low dose of hydrochlorothiazide should be added and/or the dose of Losartan tablet should be increased to 100 mg once daily based on blood pressure response.

Paralel

tablets 5 mg/10 mg



Description: white or off-white, flat-faced tablets, bevelled and scored on one side.

Composition: each tablet contains:

active substance: amlodipine (as amlodipine besilate) – 5 mg and lisinopril (as lisinopril dihydrate) – 10 mg;

excipients: sodium starch glycolate (type A), magnesium stearate, microcrystalline cellulose.

Pharmacotherapeutic group: Antihypertensive agent. Combination of a selective calcium channel blocker with a predominant vascular effect and an angiotensin-converting enzyme inhibitor.

ATC code: C09BB03.

Therapeutic indications

Essential hypertension.

Mode of administration and doses

The drug product is prescribed in case if the desired level of blood pressure cannot be achieved during monotherapy with one of the drug product components.

Adult dose (as monotherapy) – 1 tablet per day, regardless of the meal. Depending on the individual sensitivity, the dose can be increased up to 2 tablets per day.

Atorvastatin

film-coated tablets 10 mg, 20 mg

International non-proprietary name: Atorvastatin.

Description: white or off-white film-coated tablets, biconvex.

Composition: each film-coated tablet contains:

active substance: atorvastatin (as atorvastatin calcium salt) – 10 mg or 20 mg;

excipients: lactose monohydrate, microcrystalline cellulose (E-460), crosscarmellose sodium (E-468), hypromellose 2910 (E-463), polysorbate 80 (E-433), calcium stearate (E-470), calcium carbonate (E-170), titanium dioxide (E-171), talc (E-553).

Pharmacotherapeutic group: Hypocholesterolemic and antitrigliceridemic agent. HMG-CoA reductase inhibitor (statin).

ATC code: C10AA05.

Therapeutic indications

Hypercholesterolemia

Atorvastatin is prescribed as a supplement to diet for treating patients with increased total cholesterol, LDL (low density lipoprotein) cholesterol, apolipoprotein B and triglycerides, as well as for increasing the level of HDL (high density lipoprotein) cholesterol in patients with primary hypercholesterolemia (familial heterozygous and non-familial hypercholesterolemia), combined (mixed) hyperlipidemia (Fredrickson type IIa and IIb), increased plasma triglycerides (Fredrickson type III) when the diet has no sufficient effect. Atorvastatin is also indicated

for lowering total cholesterol and LDL cholesterol in patients with homozygous familial hypercholesterolemia with insufficient response to the diet and other non-pharmaceutical therapies.

Cardiovascular complications prevention

Atorvastatin is indicated for patients without clinical signs of a cardiovascular diseases, with or without dyslipidemia, but with multiple risk factors of coronary heart disease, such as smoking, arterial hypertension, diabetes mellitus, low HDL cholesterol or with family history of premature coronary heart disease:

- to reduce the risk of lethality in coronary heart disease and nonfatal myocardial infarction;
- to reduce the risk of stroke;
- to reduce the risk to undergo revascularization and the risk of angina pectoris;
- to reduce the risk of hospital admission with chronic heart failure;
- to reduce the risk of angina pectoris.

Mode of administration and doses

Orally, at any time of the day, with or without food. Before the beginning of therapy, the patient should take to the diet ensuring lowering of blood lipids and should follow it throughout the whole treatment period.

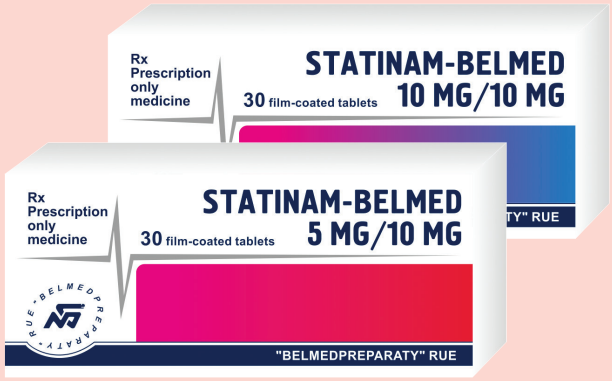
Coronary heart disease prevention: initial adult dose is 10 mg once a day. The dose should be changed with the interval of at least 2-4 weeks while monitoring blood lipids. Maximum daily dose is 80 mg at once. In case of concomitant administration with cyclosporine, the maximum daily dose of atorvastatin amounts to 10 mg; with clarithromycin – 20 mg; with itraconazole – 40 mg.

Primary hypercholesterolemia and combined (mixed) hyperlipidemia: 10 mg once a day. The effect is observed within 2 week, the maximum effect is observed within 4 weeks.

Homozygous familial hypercholesterolemia: 80 mg once a day (lowering of LDL by 18-45%). Before the beginning of therapy, the patient should be prescribed a standard hypocholesterolemic diet which they should follow throughout the treatment period. In hepatic failure, the doses should be lowered. The initial dose for children aged 10-17 (only boys and menstruant girls) in heterozygous familial hypercholesterolemia is 10 mg once a day. The dose should be increased no sooner than in 4 weeks. The maximum daily dose is 20 mg (administration of doses over 20 mg has not been studied).

Statinam

film-coated tablet 5 mg/10 mg, 10 mg/10 mg



Description: white to almost white, round, biconvex, film-coated tablets.

Composition: each film-coated tablet contains:

active substance: amlodipine (asamlodipine besilate) – 5 mg or 10 mg; atorvastatin (as atorvastatin calcium) – 10 mg;

excipients: pregelatinised starch, calcium carbonate, croscarmellose sodium, hypromellose 2910, anhydrous colloidal silicon dioxide, calcium stearate, microcrystalline cellulose, opadry II white (85F).

Ingredients of opadry II white (85F): partially hydrolyzed polyvinyl alcohol, macrogol/polyethyleneglycol; talc (E553b), titanium dioxide (E171).

Pharmacotherapeutic group: HMG-CoA reductaseingibitors (statins), different combinations, atorvastatin and amlodipine.

ATC code: C10BX03.

Therapeutic indications

Statinam is prescribed to the patients to whom the simultaneous treatment with amlodipine and atorvastatin is recommended.

Mode of administration and doses

For treatment of hypertension/stenocardia and hyperlipidemia the dose of Statinam is selected individually taking into consideration the effectiveness and acceptability of each component of the drug product. Statinam tablets are indivisible and cannot be administered in the period of amlodipine dose titration, starting with 2.5 mg. If amlodipine dose titration, starting with 2.5 mg or atorvastatin administration in dose that exceeds 10 mg is necessary, it is recommended to administer monocomponent drug products such as: amlodipine and atorvastatin in the corresponding dose.