APPROVED
Order of Ministry of
Health of Ukraine
30.08.2018 № 1572
Registration certificate
№ UA/13322/01/02
№ UA/13322/01/03

INSTRUCTION
for medical use

HYPOTEL®

Composition:
active substance: telmisartan;
1 tablet contains telmisartan 40 mg or 80 mg;
excipients: sodium hydroxide, meglumine, mannitol (E 421), crospovidone, magnesium stearate.

Pharmaceutical form. Tablets.
Basic physico-chemical properties: white or almost white, round biconvex tablets.

Pharmacotherapeutic group. Angiotensin II receptor blockers, plain.
ATC code C09C A07.
Pharmacological properties.
Pharmacodynamics.
Mechanism of action. Telmisartan is a specific and effective angiotensin II receptor (type AT_1) blocker for oral use.
Telmisartan displaces angiotensin II with very high affinity from its binding site at the AT_1 receptor subtype, which is responsible for the action of angiotensin II.
Telmisartan does not exhibit any partial agonist effect on the AT_1 receptor. Telmisartan selectively binds the AT_1 receptor. The binding is long-lasting. Telmisartan does not show affinity for other receptors, including AT_2 and other less studied AT receptors. The functional role of these receptors is not known, nor is the effect of their possible overstimulation by angiotensin II, whose levels are increased by telmisartan. Plasma aldosterone levels are decreased by telmisartan. Telmisartan does not inhibit human plasma renin or block ion channels. Telmisartan does not inhibit angiotensin converting enzyme (kininase II), the enzyme which also degrades bradykinin. Therefore, it is not expected to potentiate bradykinin-mediated adverse events.
In humans, an 80 mg dose of telmisartan almost completely inhibits the angiotensin II evoked blood pressure increase. The inhibitory effect is maintained over 24 hours and remains measurable up to 48 hours.
Pharmacokinetics.
Absorption. The absorption of telmisartan is rapid although the amount of the drug absorbed varies. The mean absolute bioavailability for telmisartan is about 50 %. When telmisartan is taken with food, the reduction in the area under the "plasma concentration — time" curve (AUC_0 $AUC_{0-\infty}$) of telmisartan varies from approximately 6 % (40 mg) to 19 % (160 mg). By 3 hours after administration, plasma concentrations are similar to those of telmisartan taken without food.
Linearity/Non-linearity. The small reduction in AUC is not expected to cause a reduction in the therapeutic efficacy. There is no linear relationship between the dose and plasma level. C_{max} and to a lesser extent AUC increase disproportionately at doses above 40 mg.
Distribution. Telmisartan is largely bound to plasma protein (>99.5 %), mainly albumin and alpha-1 acid glycoprotein. The mean steady state apparent volume of distribution (V_{ss}) is approximately 500 l.
Biotransformation. Telmisartan is metabolized by conjugation to the glucuronide of the parent

compound. No pharmacological activity has been shown for the conjugate.
Elimination. Telmisartan is characterized by biexponential decay pharmacokinetics with a terminal elimination half-life of > 20 hours. The maximum plasma concentration (C_{max}) and, to a smaller extent, the area under the "plasma concentration — time" curve (AUC), increase disproportionately with dose. There is no evidence of clinically relevant accumulation of telmisartan taken at the recommended dose. Plasma concentrations were higher in females than in males, without relevant influence on efficacy.
Following oral (and intravenous) administration, telmisartan is nearly exclusively excreted with the feces, mainly as an unchanged compound. Cumulative renal excretion is < 1 % of the dose. Total plasma clearance (Cl_{tot}) is high (approximately 1,000 ml/min) compared with hepatic blood flow (about 1,500 ml/min).
Special groups of patients.
Children. The pharmacokinetics of two doses of telmisartan were assessed as a secondary objective in hypertensive patients (n = 57) aged 6 to < 18 years after taking telmisartan at a dose of 1 mg/kg or 2 mg/kg over a 4-week treatment period. Pharmacokinetic objectives included the determination of the steady-state of telmisartan in children and adolescents, and investigation of age-related differences. Although the study was too small for a meaningful assessment of the pharmacokinetics of children under 12 years of age, the results are generally consistent with the findings in adults and confirm the non-linearity of telmisartan, particularly for C_{max}.
Gender. The plasma C_{max} and AUC in women were approximately 3- and 2-fold higher, respectively, than in males.
Elderly patients. The pharmacokinetics of telmisartan do not differ between elderly patients and patients under 65 years of age.
Renal impairment. In patients with mild, moderate and severe renal impairment, a 2-fold increase of plasma concentrations was observed. However, lower plasma concentrations were observed in patients with renal insufficiency undergoing dialysis. Telmisartan is highly bound to plasma protein in patients with renal insufficiency and cannot be removed by dialysis. The elimination half-life is not changed in patients with renal impairment.
Hepatic impairment. Pharmacokinetic studies in patients with hepatic impairment showed an increase in absolute bioavailability up to nearly 100 %. The elimination half-life is not changed in patients with hepatic impairment.

Clinical characteristics.
Indications.
Hypertension.
Use for treatment of essential hypertension in adults.
Prevention of cardiovascular diseases.
Use for reduction of cardiovascular morbidity in adults with:
- manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease);
- type 2 diabetes mellitus with documented target organ damage.

Contraindications.
Hypersensitivity to the active substance or to any of the excipients of the drug (see section "Composition");
- pregnancy or planned pregnancy (see sections "Administration details", "Use during pregnancy or breastfeeding");
- obstructive biliary disorders;
- severe hepatic impairment;
- children's age (under 18 years).
The concomitant use of telmisartan with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m^2) (see sections "Pharmacological properties" and "Interaction with other medicinal product and other forms of interaction").

Interaction with other medicinal products and other forms of interaction.

Digoxin.

When telmisartan was co-administered with digoxin, median increases in digoxin peak plasma concentration (49 %) and in trough concentration (20 %) were observed. When initiating, adjusting, and discontinuing telmisartan, monitor digoxin levels in order to maintain levels within the therapeutic range.

As with other medicinal products acting on the renin-angiotensin-aldosterone system, telmisartan may provoke hyperkalemia (see section "Administration details"). The risk may increase in case of treatment combination with other medicinal products that may also provoke hyperkalemia (potassium-containing salt substitutes, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor blockers, non-steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim).

The occurrence of hyperkalemia depends on associated risk factors. The risk is increased in case of the above-mentioned treatment combinations. The risk is particularly high in combination with potassium-sparing diuretics, and when combined with potassium-containing salt substitutes. A combination with ACE inhibitors or NSAIDs, for example, presents a lesser risk provided that precautions for use are strictly followed.

Concomitant use not recommended.

Potassium-sparing diuretics or potassium supplements. Angiotensin II receptor blockers such as telmisartan attenuate diuretic-induced potassium loss. Potassium-sparing diuretics e.g. spironolactone, eplerenone, triamterene, or amiloride, potassium supplements, or potassium-containing salt substitutes may lead to a significant increase in serum potassium. If concomitant use is indicated because of documented hypokalemia, they should be used with caution and with frequent monitoring of serum potassium.

Lithium. Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with ACE inhibitors, and with angiotensin II receptor blockers, including telmisartan. If use of this combination is necessary, careful monitoring of serum lithium levels is recommended.

Concomitant use requiring caution.

Non-steroidal anti-inflammatory medicinal products. NSAIDs (i.e. acetylsalicylic acid at anti-inflammatory doses, COX-2 inhibitors and non-selective NSAIDs) may reduce the antihypertensive effect of angiotensin II receptor blockers.

In some patients with renal impairment (e.g. dehydrated patients or elderly patients with renal impairment), the co-administration of angiotensin II receptor blockers and agents that inhibit cyclo-oxygenase may result in further deterioration of renal function, including possible acute renal failure, which is usually reversible.

Therefore, this combination should be used with caution, especially in elderly patients. Patients should be adequately hydrated, and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically after its discontinuation.

In one study the co-administration of telmisartan and ramipril led to an up to 2.5-fold increase in the AUC_{0-24} and C_{max} of ramipril and ramiprilat. The clinical relevance of this observation is not known.

Diuretics (thiazide or loop diuretics). Prior treatment with high dose diuretics such as furosemide (loop diuretic) and hydrochlorothiazide (thiazide diuretic) may result in dehydration and in development of hypotension when initiating therapy with telmisartan.

To be taken into account with concomitant use.

Other antihypertensive agents. The blood pressure lowering effect of telmisartan can be increased by concomitant use of other antihypertensive medicinal products.

Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone system (RAAS) through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalemia and decreased renal function (including acute renal failure) compared to the use of a single RAAS-acting agent (see sections "Pharmacokinetics", "Contraindications" and "Administration details").

Based on the pharmacological properties of baclofen and amifostine, it can be expected that these medicinal products may potentiate the hypotensive effects of all antihypertensives including telmisartan.

Furthermore, orthostatic hypotension may be aggravated by the use of alcohol, barbiturates, narcotics, or antidepressants.
Corticosteroids (systemic use). Reduction of the antihypertensive effect.

Administration details.
Pregnancy. Angiotensin II receptor blockers should not be initiated during pregnancy. Unless continued angiotensin II receptor blocker therapy is considered essential, patients planning pregnancy should be changed to alternative antihypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor blockers should be stopped immediately, and, if appropriate, alternative therapy should be started (see sections "Contraindications" and "Using during pregnancy or breastfeeding").
Hepatic impairment.
Hypotel is not to be given to patients with cholestasis, biliary obstructive disorders or severe hepatic impairment (see section "Contraindications") since telmisartan is mostly eliminated with the bile. Patients with these disorders can be expected to have reduced hepatic clearance for telmisartan.
Telmisartan should be used only with caution in patients with mild to moderate hepatic impairment.
Renovascular hypertension. There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.
Renal impairment and kidney transplantation. When telmisartan is used in patients with impaired renal function, periodic monitoring of potassium and creatinine serum levels is recommended. There is no experience regarding the administration of Telmisartan in patients with recent kidney transplantation.
Telmisartan is not removed from blood by hemofiltration and is not dialyzable.
Patients with volume depletion and/or sodium depletion. Symptomatic hypotension, especially after the first dose of telmisartan, may occur in patients who are volume and/or sodium depleted as a result of vigorous diuretic therapy, dietary salt restriction, or diarrhea and vomiting. Such conditions should be corrected before the administration of the drug Hypotel. Sodium and/or volume depletion should be corrected prior to administration of telmisartan
Dual blockade of the renin-angiotensin-aldosterone system. There is evidence that the concomitant use of angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers or aliskiren increases the risk of hypotension, hyperkalemia and decreased renal function (up to acute renal failure). Dual blockade of RAAS through the combined use of ACE inhibitors, angiotensin II receptor blockers or aliskiren is therefore not recommended (see sections "Interaction with other medicinal products and other forms of interaction").
If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and blood pressure.
ACE inhibitors and angiotensin II receptor blockers should not be used concomitantly in patients with diabetic nephropathy.
Other conditions with stimulation of the renin-angiotensin-aldosterone system. In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), the use of medicinal products that affect this system, such as telmisartan, has been associated with acute hypotension, hyperazotemia, oliguria, or rarely acute renal failure (see section "Adverse reactions").
Primary aldosteronism. Patients with primary aldosteronism generally will not respond to antihypertensive medicinal products acting through inhibition of the renin-angiotensin system. Therefore, the use of telmisartan is not recommended in such patients.
Aortic and mitral valve stenosis, obstructive hypertrophic cardiomyopathy. As with other vasodilators, special caution is indicated in patients suffering from aortic or mitral stenosis, or obstructive hypertrophic cardiomyopathy.
Diabetic patients treated with insulin or antidiabetics. Hypoglycemia may occur during telmisartan treatment in diabetic patients treated with insulin or antidiabetics. Appropriate blood glucose monitoring should be considered in such patients, and dose adjustment of insulin or antidiabetics may be required.

Hyperkalemia. The use of medicinal products that affect the renin-angiotensin-aldosterone system may cause hyperkalemia.
In elderly patients, in patients with renal insufficiency, in patients with diabetes mellitus, in patients concomitantly treated with other medicinal products that may increase potassium levels, and/or in patients with intercurrent disease, hyperkalemia may be fatal.
Before considering the concomitant use of medicinal products that inhibit the renin-angiotensin-aldosterone system, the benefit-risk ratio should be evaluated.
The main risk factors for hyperkalemia to be considered are:
- Diabetes mellitus, renal impairment, age over 70 years.
- Combination therapy with one or more other medicinal products that affect the renin-angiotensin-aldosterone system and/or potassium supplements. Medicinal products or therapeutic classes of medicinal products that may provoke hyperkalemia are potassium-containing salt substitutes, potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor blockers, non-steroidal anti-inflammatory medicinal products (NSAIDs, including selective COX-2 inhibitors), heparin, immunosuppressives (cyclosporin or tacrolimus), and trimethoprim.
- Intercurrent events, in particular dehydration, acute cardiac decompensation, metabolic acidosis, worsening of renal function, sudden worsening of the renal condition (e.g. infectious diseases), cellular lysis (e.g. acute limb ischemia, rhabdomyolysis, major trauma).

Close monitoring of serum potassium is recommended in patients at risk (see section “Interaction with other medicinal products and other forms of interaction”).
Ethnic differences. As observed for angiotensin-converting enzyme inhibitors, telmisartan and other angiotensin II receptor blockers are apparently less effective in lowering blood pressure in black people than in non-blacks. This may be due to higher prevalence of low-renin states in the black hypertensive population.
Ischemic heart disease. As with any antihypertensive agent, excessive reduction of blood pressure in patients with ischemic heart disease or ischemic cardiopathy could result in a myocardial infarction or stroke.
Intestinal angioedema. Intestinal angioedema has been reported in patients treated with angiotensin II receptor blockers, (see section “Adverse reactions”). These patients presented with abdominal pain, nausea, vomiting and diarrhea. Symptoms resolved after discontinuation of angiotensin II receptor blockers. If intestinal angioedema is diagnosed, telmisartan should be discontinued and appropriate monitoring should be initiated until complete resolution of symptoms has occurred.
Content. This medicinal product contains less than 1 mmol sodium (23 mg) /dose, that is to say essentially sodium-free.

Use during pregnancy or breastfeeding.
Pregnancy.

The medicinal product is contraindicated in pregnant women or women planning to conceive. If during treatment with this medicinal product pregnancy is confirmed, its use must be stopped immediately and, if necessary, replaced by another medicinal agent permitted for use during pregnancy (see sections «Contraindications» and «Administration details»).

There are no adequate data on the use of telmisartan in pregnant women.
Animal studies have shown reproductive toxicity.
Epidemiological evidence regarding the risk of teratogenicity following exposure to ACE inhibitors during the first trimester of pregnancy has not been conclusive, however a small increase in risk cannot be excluded. Whilst there is no controlled epidemiological data on the risk of teratogenicity with angiotensin II receptor blockers, similar risks may exist for this class of medicinal products. Unless continued angiotensin II receptor blocker therapy is considered essential, patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with angiotensin II receptor blockers should be stopped immediately, and, if appropriate, alternative therapy should be started.
Exposure to angiotensin II receptor blocker therapy during the second and third trimesters of pregnancy is known to induce human fetotoxicity (decreased renal function, oligohydramnios, skull ossification

retardation) and neonatal toxicity (renal failure, hypotension, hyperkalemia).
Should exposure to angiotensin II receptor blockers have occurred starting from the second trimester of pregnancy, ultrasound check of the renal function and skull of the fetus is recommended.
Infants whose mothers have taken angiotensin II receptor blockers should be closely observed for hypotension (see section "Contraindications" and "Administration details").
Breastfeeding.
Because no information is available regarding the use of telmisartan during breastfeeding, this medicinal product is not recommended for use in breastfeeding women. Alternative treatments with better established safety profiles are preferable, especially while nursing a newborn or preterm infant.
Fertility.
In preclinical studies, no effects of telmisartan on male and female fertility were observed.

Effect on reaction rate when driving motor transport or using other mechanisms.
When driving motor transport or operating other mechanisms it should be taken into account that syncope or vertigo may occur when taking antihypertensive therapy, including the drug Hypotel.

Dosage and administration.
Treatment of hypertension.
The usually effective dose is 40 mg of telmisartan once daily. Some patients may already benefit at a daily dose of 20 mg of telmisartan (use other dosage forms with the appropriate dosage). In cases where the blood pressure is not lowered to the target level, the dose of telmisartan can be increased to a maximum of 80 mg once daily. When making a decision to raise the dose, it must be borne in mind that the maximum antihypertensive effect is generally attained 4–8 weeks after the start of treatment (see section "Pharmacological properties. Pharmacodynamics").
Alternatively, telmisartan may be used in combination with thiazide diuretics such as hydrochlorothiazide, which has been shown to have an additive blood pressure lowering effect with telmisartan.
Prevention of cardiovascular diseases.
The recommended dose is 80 mg once daily. It is not known whether doses lower than 80 mg of telmisartan are effective in reducing cardiovascular morbidity.
When initiating telmisartan therapy for the reduction of cardiovascular morbidity, close monitoring of blood pressure is recommended, and if appropriate adjustment of medicinal products that lower blood pressure may be necessary.
Elderly patients. No dose adjustment is necessary for elderly patients.
Renal impairment. Limited experience is available in patients with renal impairment or undergoing hemodialysis. The lowest starting dose of 20 mg of telmisartan is recommended in such patients (use other dosage forms with the appropriate dosage; see section "Administration details"). No dose adjustment is required for patients with mild to moderate renal impairment.
Telmisartan is not removed from blood by hemofiltration and is not dialyzable.
Hepatic impairment. Hypotel is contraindicated in patients with severe hepatic impairment (see section "Contraindications").
In patients with mild to moderate hepatic impairment, the daily dose of telmisartan should not exceed 40 mg once daily (see section "Administration details").
Administration.
Telmisartan in tablet form should be taken orally once a day with or without food. Tablets should be swallowed whole with a sufficient amount of liquid.
Precautions regarding storage and administration of the medicinal product.
Telmisartan should be stored in the sealed blister to protect it from humidity. Tablets should be removed from the blister immediately before use.

Children.
The safety and efficacy of the drug Hypotel in children (under 18 years of age) have not been established. Currently available data are described in sections "Pharmacokinetics" and "Pharmacodynamics" but no

recommendations on the posology can be made.

Overdose.
There is limited information available with regard to overdose in humans.
Symptoms. The most prominent manifestations of telmisartan overdose were hypotension and tachycardia; bradycardia, dizziness, increase in serum creatinine, and acute renal failure have also been reported.
Treatment. Telmisartan is not removed from blood by hemofiltration and is not dialyzable. The patient should be closely monitored, and the treatment should be symptomatic and supportive. Treatment depends on the time since the overdosage and the severity of the symptoms. Induction of emesis and/or gastric lavage are recommended. Activated charcoal may be useful in the treatment of overdose. Serum electrolytes and creatinine should be monitored frequently. If hypotension occurs, the patient should be placed in a supine position, with salt and volume replacement given quickly.

Adverse reactions.
Serious adverse reactions, such as anaphylactic reaction and angioedema, may occur rarely (≥ 1/10,000 to <1/1,000); acute renal failure was also observed.
The overall incidence of adverse reactions reported with telmisartan was usually comparable to placebo (41.4 % vs 43.9 %) in controlled clinical trials in patients with hypertension. The incidence of adverse reactions was not dose-related, showed no correlation with gender, age or race of the patients. The safety profile of telmisartan used for reduction of cardiovascular morbidity was consistent with that obtained in hypertensive patients.
The adverse reactions listed below have been accumulated from controlled clinical trials in patients treated for hypertension and from post-marketing reports. The listing also takes into account serious adverse reactions and adverse reactions leading to discontinuation reported in three clinical long-term studies including 21,642 patients receiving telmisartan for reduction of cardiovascular morbidity for up to six years.
Adverse reactions are listed according to their frequency: very common (≥1/10); common (from 1/100 to <1/10); uncommon (from 1/1,000 to <1/100); rare (from 1/10,000 to <1/1,000); very rare (< 1/10,000). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.
Infections and infestations:
uncommon — urinary tract infections, cystitis; upper respiratory tract infections, including pharyngitis and sinusitis;
rare — sepsis including fatal outcome[1].
Blood and the lymphatic system disorders: uncommon — anemia;
rare — eosinophilia, thrombocytopenia.
Immune system disorders:
rare — anaphylactic reaction, hypersensitivity.
Metabolism disorders:
uncommon — hyperkalemia;
rare – hypoglycemia (in patients with diabetes mellitus), hyponatremia.
Psychiatric disorders:
uncommon — insomnia, depression;
rare — anxiety.
Nervous system disorders:
uncommon — syncope;
rare — somnolence.
Eye disorders:
rare — visual disturbance.
Ear and labyrinth disorders:
uncommon — vertigo.
Cardiac disorders:
uncommon — bradycardia;

rare — tachycardia.
Vascular disorders:
uncommon — hypotension[2], orthostatic hypotension.
Respiratory, thoracic and mediastinal disorders:
uncommon — dyspnea, cough;
very rare — interstitial lung disease[4].
Gastrointestinal disorders:
uncommon — abdominal pain, diarrhea, dyspepsia , flatulence, vomiting;
rare — dry mouth, stomach discomfort, dysgeusia.
Hepatobiliary disorders:
rare — hepatic function abnormal/liver disorder[3].
Skin and subcutaneous tissue disorders:
uncommon — pruritus, hyperhidrosis, rash;
rare — angioedema (including with fatal outcome), eczema, erythema, urticaria, drug eruption, toxic skin eruption.
Muscoloskeletal and connective tissue disorders:
uncommon — back pain (e.g. sciatica), muscle spasms, myalgia;
rare — arthralgia, pain in extremity, tendon pain (tendonitis-like symptoms).
Urinary system disorders:
uncommon — renal impairment (including acute renal failure).
General disorders:
uncommon — chest pain, asthenia (weakness);
rare — influenza-like symptoms.
Investigations:
uncommon — blood creatinine elevated; rare — hemoglobin decreased, blood uric acid increased, hepatic enzymes increased, blood creatine phosphokinase increased.
[1, 2, 3, 4] For further descriptions see sub-section "Description of selected adverse reactions" below.

Description of selected adverse reactions
Sepsis. In the PRoFESS trial, an increased incidence of sepsis was observed with telmisartan compared with placebo. This may be a chance finding or related to a mechanism currently not known
Hypotension. This adverse reaction was reported as common in patients with controlled blood pressure who were treated with telmisartan for the reduction of cardiovascular morbidity in addition to standard care.
Hepatic function abnormal / liver disorder. Most cases of abnormal hepatic function abnormal / liver disorder from post-marketing experience occurred in Japanese patients. These patients are more likely to experience these adverse reactions.
Interstitial lung disease. Cases of interstitial lung disease have been reported from post-marketing experience in temporal association with the intake of telmisartan. However, a causal relationship has not been established.
Intestinal angioedema. Cases of intestinal angioedema have been reported after the use of angiotensin II receptor blockers (see section "Administration details").
Reporting of suspected adverse reactions
Reporting adverse reactions after the registration of the medicinal product is of great importance. It allows to monitor the correlation of the benefits and risks related to the use of the medicinal product. Healthcare and pharmaceutical professionals, as well as patients or their legal representatives are asked to report any suspected adverse reactions and lack of efficacy of the medicinal product through the Automated pharmacovigilance information system available at: https://aisf.dec.gov.ua.

Shelf-life.
3 years.

Storage conditions.
Store in the original package at a temperature not more than 25 ºC.

Keep out of reach of children.

Packaging.
10 tablets are in a blister; 3 blisters are in a carton package.
14 tablets are in a blister; 2 or 4, or 6 blisters are in a carton package

Conditions of supply.
Prescription only.

Manufacturer.
LLC “KUSUM PHARM”.

Address of manufacturer and manufacturing site.
40020, Ukraine, Sumy region, Sumy, Skryabina Str., 54.

Last revision date.
19.05.2025