APPROVED
Order of Ministry of
Health of Ukraine
12.06.2017 No. 651
Registration certificate
No. UA/12330/01/02

AMENDED
Order of Ministry of
Health of Ukraine
11.12.2023 № 2101

INSTRUCTION
for medical use

LARFIX®

Composition:
active substance: lornoxicam;
1 tablet contains 8 mg of lornoxicam;
excipients: lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate, Opadry 03F58750 white.*
* Opadry 03F58750 white: talc, polyethylene glycol, hydroxypropyl methylcellulose, titanium dioxide (E 171).

Pharmaceutical form. Film-coated tablets.
Main physico-chemical properties: white to yellowish oval-shaped oblong film-coated tablet with imprint "L8" on one side and plain on the other.

Pharmacotherapeutic group. Anti-inflammatory and antirheumatic products, non-steroids.
ATC Code: M01A C05.

Pharmacological properties.
Pharmacodynamics.
Lornoxicam is a non-steroidal anti-inflammatory drug (NSAID) with analgesic properties and belongs to the class of oxicams.
Mechanism of action. Lornoxicams inhibits the prostaglandin synthesis (inhibition of the cyclooxygenase enzyme) leading to desensitisation of peripheral nociceptors and consequently inhibition of inflammation. A central effect on nociception which seems to be independent of anti-inflammatory effects has also been suggested. Lornoxicam has no effect on vital signs (e.g., body temperature, respiratory rate, heart rate, blood pressure, ECG, spirometry).
Due to a local gastrointestinal irritation and a systemic ulcerogenic effect related to the inhibition of prostaglandin (PG)-synthesis, gastrointestinal sequela are common undesirable effects after treatment with lornoxicam as seen with other NSAIDs.
Pharmacokinetic properties.
Absorption. Lornoxicam is absorbed rapidly and almost completely from the gastrointestinal tract. Maximum plasma concentrations (C_{max}) are achieved after approximately 1–2 hours. The absolute bioavailability of lornoxicam is 90–100%. No first-pass effect has been observed. Simultaneous intake of lornoxicam with meals reduces C_{max} by approximately 30% and T_{max} increases from 1.5 to 2.3 hours. The absorption of lornoxicam (calculated on the area under pharmacokinetic "concentration-time" curve [AUC]) can be reduced up to 20%.
Distribution. Lornoxicam is found in the plasma in unchanged form and as its inactive hydroxylated metabolite. The plasma protein binding of lornoxicam is 99% and not concentration dependent. It is

also found in synovial fluid after repeated dosing.
Biotransformation. Lornoxicam is extensively metabolised in the liver, primarily to the inactive 5–hydroxylornoxicam by hydroxylation. CYP2C9 is involved in this biotransformation of lornoxicam. Due to genetic polymorphism, slow and extensive metabolisers exist for this enzyme which could result in markedly increased plasma levels of lornoxicam in slow metabolisers. The hydroxylated metabolite exhibits no pharmacological activity. Lornoxicam is metabolised completely, and approximately 2/3 is eliminated via the liver and 1/3 via the kidneys as inactive substance.
In non-clinical studies, lornoxicam did not induce liver enzymes. There is no evidence of accumulation of lornoxicam after repeated administrations, when given according to recommended dosage.
Elimination. The mean elimination half-life of the parent compound is 3 to 4 hours. After oral administration about 50% is excreted in the feces and 42% through the kidneys, mainly as 5-hydroxylornoxicam. The elimination half-life of 5-hydroxylornoxicam is about 9 hours after a parenteral single or twice daily dose. There is no evidence that elimination rate changes with repeat dose administration.
Special populations.
In elderly patients (above age 65), the clearance is reduced with 30–40%. Apart from reduced clearance, there is no significant change in the kinetic profile of lornoxicam in elderly patients. There is no significant change in the kinetic profile of lornoxicam in patients with renal or hepatic failure, except for accumulation in patients with chronic liver disease after 7 days of treatment with daily doses of 12 and 16 mg.

Clinical characteristics.
Indications.
- Short-term symptomatic treatment of acute mild to moderate pain in adults.
- Symptomatic treatment of pain and inflammation in osteoarthritis in adults.
- Symptomatic treatment of pain and inflammation in rheumatoid arthritis in adults.

Contraindications.
- Hypersensitivity to lornoxicam or to any of the excipients.
- Thrombocytopenia.
- Hypersensitivity (symptoms like asthma, rhinitis, angioedema or urticaria) to other NSAIDs including acetylsalicylic acid.
- Severe heart failure.
- Gastrointestinal bleeding, cerebrovascular bleeding or other bleeding disorders.
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- Active recurrent peptic ulcer/hemorrhage or history of recurrent peptic ulcer/hemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- Severe hepatic impairment.
- Severe renal impairment (serum creatinine >700 μmol/L).
- The third trimester of pregnancy (see "Pregnancy and lactation" section).

Interaction with other medicinal products and other forms of interaction.
Concomitant administration of lornoxicam:
Cimetidine: increased plasma concentrations of lornoxicam, which may increase the risk of adverse effects of lornoxicam (no interaction between lornoxicam and ranitidine, or lornoxicam and antacids has been demonstrated).
Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see "Special warnings and precautions for use" section). Careful monitoring of international normalised ratio (INR) level should be undertaken.
Phenprocoumon: decreased effect of phenprocoumon treatment.
Heparin: NSAIDs increase the risk of bleeding and spinal or epidural hematomas when given concomitantly to heparin in the context of spinal or epidural anesthesia (see "Special warnings and precautions for use" section).

ACE inhibitors: the antihypertensive effect of the ACE inhibitor may decrease.
Diuretics: decreased diuretic and antihypertensive effect of loop diuretics, thiazide diuretics, and with potassium sparing diuretics (increased risk of hyperkalemia and nephrotoxicity).
Beta-adrenergic blockers: decreased antihypertensive efficacy.
Angiotensin II receptor blocker: decreased antihypertensive efficacy.
Digoxin: decreased renal clearance of digoxin, which increases risk of digoxin toxicity.
Corticosteroids: increased risk of gastrointestinal ulceration or bleeding (see "Special warnings and precautions for use" section).
Quinolone antibiotics (e.g., levofloxacin, ofloxacin): increased risk of seizures.
Anti-platelet agents (e.g., clopidogrel): increased risk of bleeding (see "Special warnings and precautions for use" section).
Other NSAIDs: increased risk of gastrointestinal bleeding or ulceration.
Methotrexate: increased serum concentration of methotrexate. Increased toxicity may result. When concomitant therapy has to be used careful monitoring should be undertaken.
Selective serotonin reuptake inhibitors (SSRIs): increased risk of bleeding (see "Special warnings and precautions for use" section).
Lithium preparations: NSAIDs inhibit renal clearance of lithium, thus the serum concentration of lithium may increase above toxicity limits. Therefore, serum lithium levels require monitoring, especially during initiation, adjustment and withdrawal of treatment.
Cyclosporine: increased serum concentration of cyclosporine. Nephrotoxicity of cyclosporine may be enhanced via renal prostaglandin mediated effects. During combined treatment renal function should be monitored.
Sulphonylureas (e.g. glibenclamide): increased risk of hypoglycemia.
Known inducers and inhibitors of CYP2C9 isoenzymes: lornoxicam (as other NSAIDs depending on the cytochrome P450 2C9 (CYP2C9 isoenzyme)) has interactions with known inducers and inhibitors of CYP2C9 isoenzymes (see "Biotransformation" section).
Tacrolimus: increase the risk of nephrotoxicity owing to reduced synthesis of prostacyclin in the kidney. During combined treatment renal function should be monitored (see "Special warnings and precautions for use" section).
Pemetrexed: NSAIDs may reduce renal clearance of pemetrexed resulting in increased renal and gastrointestinal toxicity, and myelosuppression.
Food shows a delayed absorption of lornoxicam. Therefore, Larfix® tablets should not be taken with food when a quick onset of efficacy (relief of pain) is required.
Food may decrease the absorption with about 20% and increase T_{max} (see "Pharmacological properties. Pharmacokinetic properties" section).

Special warnings and precautions for use.
Lornoxicam reduces platelet aggregation and prolongs bleeding time. Consequently, caution should be taken when administering to patients with increased bleeding tendency.
Lornoxicam should only be administered after careful risk-benefit assessment in patients with:
- renal impairment: lornoxicam should be administered with caution in patients with mild (serum creatinine 150–300 μmol/L) to moderate (serum creatinine 300–700 μmol/L) renal impairment due to dependency on renal prostaglandins for maintenance of renal blood flow (see "Posology and method of administration" section). Treatment with lornoxicam should be discontinued if renal function deteriorates during treatment;
- in patients who undergo major surgery, with cardiac failure, receiving concomitant treatment with diuretics or medicinal products that are suspected to, or known to be able to cause kidney damage renal function should be monitored (see "Interaction with other medicinal products and other forms of interaction" section);
- in patients with blood coagulation disorders careful clinical monitoring and laboratory assessment is recommended (e.g., activated partial thromboplastin time);
- in patients with hepatic impairment (e.g., liver cirrhosis), clinical monitoring and laboratory assessments are recommended, as accumulation of lornoxicam (increase in AUC) may occur (see "Pharmacological properties. Pharmacokinetic properties" section) after treatment with daily doses

of 12–16 mg. Apart from that, hepatic impairment does not seem to affect pharmacokinetic parameters of lornoxicam as compared to healthy subjects.
Patients receiving long term treatment (longer than 3 months) with NSAIDs should be monitored regularly for renal and hepatic function and hematology.
In elderly patients above 65 years of age, monitoring of renal and hepatic function is recommended.
Caution is advised in elderly postoperative patients.
Concomitant NSAID use.
The use of lornoxicam with concomitant NSAIDs (including cyclooxygenase-2 selective inhibitors) should be avoided (see "Interaction with other medicinal products and other forms of interaction" section).
Minimisation of undesirable effects.
Undesirable effects may be minimised by using lowest effective dose for the shortest duration necessary to control symptoms (see "Posology and method of administration" section, and gastrointestinal and cardiovascular risks below).
Gastrointestinal bleeding, ulceration and perforation.
Gastrointestinal (GI) bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.
The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with hemorrhage or perforation (see "Contraindications" section) and in the elderly. These patients should commence treatment on the lowest dose available (see "Posology and method of administration" section).
NSAIDs should be used with caution in the treatment of these patients, and also for patients requiring concomitant low dose of acetylsalicylic acid or other medicinal products likely to increase gastrointestinal risk (see "Interaction with other medicinal products and other forms of interaction" section). Combination therapy with gastroprotective agents (e.g., misoprostol or proton pump inhibitors) should be considered for patients that require such concomitant therapy. Clinical monitoring at regular intervals is recommended.
Patients with a history of GI toxicity, particularly the elderly, should be instructed to report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.
Caution should be advised in patients receiving concomitant medicinal products, which could increase the risk of ulceration, or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as acetylsalicylic acid (see "Interaction with other medicinal products and other forms of interaction" section).
When GI bleeding or ulceration occurs in patients receiving lornoxicam, treatment should be withdrawn.
NSAIDs should be given with caution to patients with a history of GI disease (e.g., ulcerative colitis, Crohn's disease) as their condition may be exacerbated.
Elderly.
The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation, which may be fatal (see "Contraindications" section).
Cardiovascular and cerebrovascular effects.
Appropriate monitoring is required for patients with a history of hypertension and/or mild to moderate congestive heart failure, as fluid retention and oedema have been reported in association with NSAID therapy.
Clinical trial and epidemiological data suggest that use of some NSAIDs, particularly at high doses and in long term treatment, may be associated with an increased risk of arterial thrombotic events (e.g., myocardial infarction or stroke). There are insufficient data to exclude such a risk for lornoxicam.
Patients with uncontrolled hypertension, congestive heart failure, established ischemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with lornoxicam after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g., hypertension, hyperlipidemia, diabetes mellitus, smoking).

Concomitant treatment with NSAIDs and heparin in the context of a spinal or epidural anesthesia increases the risk of spinal/epidural hematoma (see “Interaction with other medicinal products and other forms of interaction” section).
Skin disorders.
Serious skin reactions, some of which are fatal, including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported very rarely in association with the use of NSAIDs (see “Adverse reactions” section). Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of reactions occurring within the first month of treatment in the majority of cases. Lornoxicam should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Respiratory disorders.
Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma as NSAIDs have been reported to precipitate bronchospasm in such patients.
Systemic lupus erythematosus and mixed connective tissue disease.
Caution is required in patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders, as there may be an increased risk of aseptic meningitis.
Nephrotoxicity.
Concomitant treatment of NSAIDs and tacrolimus may increase the risk of nephrotoxicity, due to reduced synthesis of prostacyclin in the kidney. Renal function must therefore be monitored closely in patients receiving combination therapy (see “Interaction with other medicinal products and other forms of interaction” section).
Laboratory abnormalities.
As with most NSAIDs, occasional increases in serum transaminases level, increase in serum bilirubin or other liver function parameters, as well as increases in serum creatinine and blood urea nitrogen and other laboratory abnormalities have been reported with lornoxicam. Should any such abnormality prove significant or persist the administration of lornoxicam should be stopped and appropriate investigations prescribed.
Fertility.
The use of lornoxicam, as with any drug known to inhibit cyclooxygenase / prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of lornoxicam should be considered (see “Pregnancy and lactation” section).
Varicella.
Exceptionally, varicella can be at the origin of serious cutaneous and soft tissues infectious complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of lornoxicam in case of varicella.
Excipients.
This medicinal product contains lactose. Patients with established intolerance to some sugars should consult a doctor before using the medicine.
This drug contains less than 1 mmol sodium (23 mg), that is to say essentially 'sodium-free'.

Pregnancy and lactation.
Pregnancy.
Lornoxicam is contraindicated in the third trimester of pregnancy (see “Contraindications” section) and should not be used during pregnancy in the first and second trimesters and delivery, as no clinical data on exposed pregnancies are available.
There are no adequate data from the use of lornoxicam in pregnant women. Studies in animals have shown reproductive toxicity.
Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post implantation loss and embryo-fetal lethality.

From the 20th week of pregnancy onwards, the use of lornoxicam may cause oligohydramnios resulting from fetal renal dysfunction. This condition may occur shortly after initiation of treatment and is usually reversible upon discontinuation of treatment. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment discontinuation. Therefore, lornoxicam should not be administered during the first and second trimester of pregnancy unless clearly necessary. If lornoxicam is used by a woman attempting to conceive, or during the first or second trimester of pregnancy, the dose should be kept as low as possible and the duration of treatment as short as possible. Following exposure to lornoxicam for several days from gestational week 20 onwards, prenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered. Larfix® should be discontinued in pregnant women if oligohydramnios or ductus arteriosus constriction are found.
Prostaglandin synthesis inhibitors administered during the third trimester of pregnancy may expose the fetus to:
- cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction (see above).
At the end of pregnancy, prostaglandin synthesis inhibitors may expose the mother and the fetus to:
- increased bleeding time;
- inhibition of uterine contractions, which may delay or prolong labor.
Therefore, the use of lornoxicam is contraindicated during the third trimester of pregnancy (see "Contraindications" section).
Lactation.
There are no data on the excretion of lornoxicam in breast milk of women. Lornoxicam is excreted in milk of lactating rats in relatively high concentrations. Lornoxicam should not be used in breast-feeding women.
Fertility.
The use of lornoxicam, as with any drug known to inhibit cyclooxygenase / prostaglandin synthesis, may impair fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of lornoxicam should be considered.

Effects on ability to drive and use machines.
Patients showing dizziness and/or somnolence under treatment with lornoxicam should refrain from driving or operation of machinery.

Posology and method of administration.
For all patients the appropriate dosing regimen should be based upon individual response to treatment. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see "Special warnings and precautions for use" section).
Pain
8–16 mg lornoxicam daily divided into 2 or 3 doses. Maximum recommended daily dose is 16 mg.
Osteoarthritis and rheumatoid arthritis
Initial recommended dose is 12 mg lornoxicam daily divided into 2 or 3 doses.
Maintenance dose should not exceed 16 mg lornoxicam daily.
Larfix®, film-coated tablets should be taken with a sufficient quantity of liquid.
No special dosage modification is required for elderly patients above 65 years of age unless renal or hepatic function is impaired, but lornoxicam should be administered with caution as gastrointestinal adverse effects are less well tolerated in this group.
Renal impairment. For patients with mild to moderate renal impairment the maximum recommended daily dose is 12 mg divided in 2 or 3 doses. Lornoxicam is contraindicated in patients with severe renal impairment (see "Contraindications" section).
Hepatic impairment. For patients with moderate hepatic impairment the maximum recommended daily dose is 12 mg divided in 2 or 3 doses (see "Special warnings and precautions for use" section).

Lornoxicam is contraindicated in patients with severe hepatic impairment (see "Contraindications" section).

Pediatric population.
Lornoxicam is not recommended for use in children and adolescents below 18 years of age because of a lack of data on safety and efficacy.

Overdose.
At this time, there is no experience of overdose to permit definition of the consequence of an overdose, or to suggest specific management. However, it can be expected that after an overdose with lornoxicam, the following symptoms may be observed: nausea, vomiting, cerebral symptoms (dizziness, disturbances in vision). Severe symptoms such as ataxia (ascending to coma and cramps), liver and kidney damage and potentially coagulation disorders may also occur.
In the case of a real or suspected overdose, the medicinal product should be withdrawn. Due to its short half-life, lornoxicam is rapidly excreted. Lornoxicam is not dialysable. No specific antidote is known to date. The usual emergency measures should be considered. Based on principles, only administering activated charcoal immediately after the intake of lornoxicam can lead to diminished absorption of the preparation. Gastrointestinal disorders can for example be treated with a prostaglandin analogue or ranitidine.

Adverse reactions.
The most commonly observed adverse events of NSAIDs are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur (see "Special warnings and precautions for use" section). Nausea, vomiting, diarrhea, flatulence, constipation, dyspepsia, abdominal pain, melaena, hematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration of NSAIDs. Less frequently, gastritis has been observed.
Approximately 20% of patients treated with lornoxicam can be expected to experience adverse reactions. The most frequent adverse effects of lornoxicam include nausea, dyspepsia, indigestion, abdominal pain, vomiting, and diarrhea. These symptoms have generally occurred in less than 10% of patients in available studies.
Oedema, hypertension, and cardiac failure have been reported in association with NSAID treatment.
Clinical trials and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with an increased risk of arterial thrombotic events (for example myocardial infarction or stroke) (see "Special warnings and precautions for use" section).
Exceptionally, occurrence of serious cutaneous and soft tissues infectious complications during varicella.
The following convention is used for the classification of the frequency of an adverse drug reaction: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1.000); very rare (<1/10,000), not known (cannot be estimated from the available data).
Infections and infestations: rare – pharyngitis.
Blood and lymphatic system disorders: rare – anemia, thrombocytopenia, leucopenia, prolonged bleeding time; very rare – ecchymosis. NSAIDs have been reported to cause potentially severe hematological disorders like neutropenia, agranulocytosis, aplastic anemia, and hemolytic anemia as class effects.
Immune system disorders: rare – hypersensitivity including anaphylactoid reactions and anaphylaxis.
Metabolism and nutrition disorders: uncommon – anorexia, weight changes.
Psychiatric disorders: uncommon – insomnia, depression; rare – confusion, nervousness, agitation.
Nervous system disorders: common – mild and transient headache, dizziness; rare – somnolence, paresthesia, dysgeusia, tremor, migraine; very rare – aseptic meningitis in patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorder (see "Special warnings and precautions for use" section).
Eye disorders: common – conjunctivitis; rare – visual disturbances.

Ear and labyrinth disorders: uncommon – vertigo, tinnitus.
Cardiovascular disorders: uncommon – palpitations, tachycardia, oedema, cardiac failure, flushing (see "Special warnings and precautions for use" section); rare – hypertension, hot flush, hemorrhage, hematoma.
Respiratory, thoracic and mediastinal disorders: uncommon – rhinitis; rare – dyspnea, cough, bronchospasm.
Gastrointestinal disorders: common – nausea, abdominal pain, dyspepsia, diarrhea, vomiting; uncommon – constipation, flatulence, eructation, dry mouth, gastritis, gastric ulcer, upper abdominal pain, duodenal ulcer, mouth mucosa ulceration; rare – melaena, hematemesis, stomatitis, esophagitis, gastroesophageal reflux, dysphagia, aphthous stomatitis, glossitis, perforated peptic ulcer, gastrointestinal hemorrhage.
Hepatobiliary disorders: uncommon – increase in liver function tests (ALT, AST); very rare – hepatotoxicity resulting in possible hepatic failure, hepatitis, jaundice and cholestasis.
Skin and subcutaneous tissue disorders: uncommon – rash, pruritus, hyperhidrosis, rash erythematous, urticaria, angioedema, alopecia; rare – dermatitis, eczema, purpura; very rare – oedema and bullous reactions such as erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.
Musculoskeletal and connective tissue disorders: uncommon – arthralgia; rare – bone pain, muscle spasms, myalgia.
Renal and urinary disorders: rare – nocturia, micturition disorders, increase in blood urea nitrogen and creatinine levels; very rare – lornoxicam may precipitate acute renal failure in patients with pre-existing renal impairment, who are dependent on renal prostaglandins for maintenance of renal blood flow (see "Special warnings and precautions for use" section). Nephrotoxicity in various forms including nephritis and nephrotic syndrome has been associated with NSAIDs as class effect.
General disorders and administration site conditions: uncommon – malaise, face oedema; rare – asthenia.
Reporting of suspected adverse reactions.
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Medical and pharmaceutical workers, as well as patients or their legal representatives are asked to report any suspected adverse reactions and lack of effectiveness of the medicinal product through the Pharmacovigilance Automated Information System at: https://aisf.dec.gov.ua.

Shelf life. 3 years.

Storage conditions.
Store at the temperature below 25°C.
Keep out of reach of children.

Package.
10 tablets in blister. 3 or 10 blisters in carton pack.

Conditions of supply.
By prescription.

Manufacturer.
Kusum Healthcare Pvt Ltd.

Location of manufacturer and its address of business activity.
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

Last revision date.