APPROVED
The Order of Ministry
of Health of Ukraine
11.08.2020 № 1843
Registration certificate
№ UA/9270/02/01

INSTRUCTION
for medical use

PIARON®

Composition:
active substance: paracetamol;
5 ml of suspension contains 120 mg of paracetamol;
excipients: malic acid, citric acid anhydrous, xanthan gum, maltitol liquid, sorbitol solution, sorbitol (E 420), sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), strawberry flavor, carmoisine (E122), purified water.

Pharmaceutical form. Oral suspension.
Main physical and chemical properties: viscous suspension of pink color with a strawberry odor.

Pharmacotherapeutic group. Analgesics and antipyretics. Anilides. Paracetamol.
ATC Code N02B E01.

Pharmacological properties.
Pharmacodynamics.
The drug contains paracetamol, an analgesic and antipyretic (a pain-relieving and fever-reducing drug). Its effect is based on the inhibition of prostaglandin synthesis in the CNS.
Pharmacokinetics.
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract and is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic concentrations.
Paracetamol is predominantly metabolized in the liver and excreted in the urine as metabolites. The mean plasma half-life following oral administration of paracetamol is approximately 2.3 hours.

Clinical characteristics.
Indications.
Pain during teething, toothache, sore throat, fevers in colds, influenza and pediatric infections such as chickenpox, pertussis, measles, parotitis (mumps).
The drug is also recommended for the treatment of post-vaccination hyperthermia in infants over 3 months of age.

Contraindications.
Hypersensitivity to any component of the drug, severe liver and/or kidney impairment, congenital hyperbilirubinemia, glucose-6-phosphate dehydrogenase deficiency, alcoholism, blood disease, Gilbert's syndrome, pronounced anemia, leukopenia. Children under 3 months of age.

Interaction with other medicinal products and other types of interaction.
The speed of absorption of paracetamol may be increased by metoclopramide and domperidone and reduced by colestyramine.
The anticoagulant effect of warfarin and other coumarins (with increased risk of bleeding) may be enhanced by prolonged concomitant use of paracetamol. Occasional doses have no significant effect.
Caution is advised if paracetamol is administered concomitantly with flucloxacillin as concomitant use is associated with high anion gap metabolic acidosis, particularly in patients with risk factors (see section "Administration details").
Barbiturates reduce the antipyretic effect of paracetamol.
Anticonvulsants (including phenytoin, barbiturates, carbamazepine) that stimulate the activity of microsomal liver enzymes may increase the toxic effects of paracetamol on the liver due to increased metabolism of the drug into hepatotoxic metabolites. Their toxic effect on the liver increases upon concomitant use of paracetamol with hepatotoxic agents. Concomitant use of high doses of paracetamol and isoniazid increases the risk of hepatotoxic syndrome.
Paracetamol reduces the efficacy of diuretics.
Do not use with alcohol.
High paracetamol concentrations may influence blood glucose level assessment by the glucose oxidase-peroxidase method and uric acid evaluation by the phosphotungstic acid method.

Administration details.
This medicinal product contains paracetamol. It must not be used with other products containing paracetamol and used, for example, for reducing fever, treating pain, symptoms of flu and cold, or insomnia. Concomitant use with other medicinal products containing paracetamol may result in overdose.
Paracetamol overdose may result in liver failure, which may require liver transplantation or result in death.
A doctor should be consulted before using the drug in case of liver or kidney disease, or decreased glutathione levels.
It should be taken into account that patients with liver disease are at increased risk of paracetamol-induced hepatotoxicity. If acute viral hepatitis is identified, treatment must be discontinued.
Liver dysfunction/liver impairment have been reported in patients with decreased levels of glutathione, for example, in severe emaciation, anorexia, low body mass index (BMI), chronic alcoholism, or sepsis.
Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis, particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.
In patients with low glutathione levels, the use of paracetamol is associated with a higher risk of metabolic acidosis. The symptoms of metabolic acidosis include deep, fast, or difficult breathing, nausea, vomiting, loss of appetite. A doctor should be consulted immediately if such symptoms develop.
If symptoms persist for longer than 3 days of administration or worsen, a physician should be consulted.
If the renal filtration rate is below 10 ml/min, the dosing interval must be increased to 8 hours.
Prolonged use or high doses of the medicinal product may result in hepatic or renal dysfunction, as well as blood count disorders.
The drug contains maltitol (E 965) and sorbitol solution (E 420). Each 5 ml of the suspension contains 105.0 mg of sorbitol. Patients with rare hereditary forms of fructose intolerance should

not take this medicinal product. Patients with intolerance to some sugars should consult a doctor before taking this medicinal product.
This medicinal product contains sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), strawberry flavor, carmoisine (E122), which may cause allergic reactions (possibly delayed).
Keep the drug out of sight and reach of children.

Use during pregnancy or breastfeeding.
The drug is indicated for use in children.
Pregnancy.
A large amount of data on pregnant women indicates neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.
Breastfeeding.
Paracetamol is excreted in breast milk, but not in clinically significant amounts if the drug is used at the recommended doses. Available published data do not contraindicate the use of the drug during breast-feeding.

Effect on reaction rate when driving motor transport or using other mechanisms.
The drug is indicated for use in children.
No effect on reaction rate when driving motor transport or using other mechanisms is expected.

Dosage and administration.
The drug is indicated for oral use.
Shake the bottle before use.
Do not exceed the recommended dosage. The lowest effective dose of the drug should be used. The dosing interval should be at least 4 hours.
For the relief of reaction after vaccination. Children from 3 months to 12 years of age: single dose of paracetamol – 10–15 mg/kg of body weight, maximum daily dose – 60 mg/kg of body weight. If a second dose is required, it may only be used not earlier than after 4 hours. Consult a physician ff fever persists after the second administration.
In other cases of pain and fever. Children from 3 months to 12 years of age: single dose of paracetamol – 10–15 mg/kg of body weight. If a second dose is required, it may only be used not earlier than after 4 hours, maximum daily dose – 60 mg/kg of body weight. Do not use more than 4 doses in 24 hours. The drug should not be used for more than 3 days without consulting a physician.
The approximate dosage of the drug depending on the child's body weight and age is provided in the table below, but in any case, make sure that the dosage does not exceed 10–15 mg of paracetamol per kilogram of body weight.

Body weight, kg	Age	Single dose, ml
6–8	3–6 months	3,5–4
8–10	6–12 months	4,5–5
10–13	1–2 years	6–6,5
13–15	2–3 years	7–8
15–21	3–6 years	9–10
21–29	6–9 years	13–14
29–42	9–12 years	18–19

Consult a doctor before initiating this medicinal product in children with kidney and liver dysfunction. This is due to the presence of paracetamol in this medicinal product.

Children.
Must not be used in children under 3 months of age. Recommended for use in children from 3 months to 12 years of age.

Overdose.
Paracetamol overdose may result in liver failure, which may require liver transplantation or result in death. Based on experience, clinical symptoms of liver damage following paracetamol overdose usually appear within 24–48 hours after the overdose and peak after 4–6 days.
Immediate medical attention is required in case of an overdose. Treatment should be initiated immediately, and the patient should be transferred to a hospital, even if there are no early symptoms of overdose.
Symptoms of overdose within the first 24 hours include: pallor, nausea, vomiting, loss of appetite, and abdominal pain. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, hemorrhage, hypoglycemia, coma, and death. Acute renal failure with acute tubular necrosis may manifest as severe loin pain, hematuria, proteinuria, and may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have also been reported, usually accompanied by liver dysfunction and hepatotoxicity.
Long-term use of high doses of the drug may result in such disorders of hematopoietic organs as aplastic anemia, pancytopenia, agranulocytosis, neutropenia, leukopenia, thrombocytopenia. Central nervous system disorders associated with high doses include dizziness, psychomotor agitation, and disorientation; urinary system disorders include nephrotoxicity (renal colic, interstitial nephritis, capillary necrosis).
Symptoms may be limited to nausea or vomiting or may not reflect the severity of overdose or the risk of organ damage.
Immediate medical attention is required in case of an overdose. Treatment of an overdose or even suspected overdose should be initiated immediately, the patient should be transferred to a hospital, even if there are no early symptoms of overdose, as liver damage may not develop immediately. Treatment with N-acetylcysteine or methionine should be considered.

Adverse reactions.
Paracetamol adverse reactions are rare. Adverse reactions observed during the broad post-marketing experience and believed to be associated with paracetamol are listed below with reference to the respective organ system and frequency.
Blood and lymphatic system disorders (rare: < 1/10000): thrombocytopenia.
Immune system disorders: (rare: < 1/10000): anaphylaxis, hypersensitivity skin reactions, including cutaneous rash, angioedema, Stevens–Johnson syndrome and toxic epidermal necrolysis.
Respiratory, thoracic, and mediastinal disorders (rare: < 1/10000): bronchospasm in patients susceptible to acetylsalicylic acid and other non-steroidal anti-inflammatory drugs.
Hepatobiliary disorders (rare: < 1/10000): hepatic impairment.
Medicinal products containing paracetamol are also associated with the following adverse reactions: pruritus, exudative erythema multiforme, nausea, epigastric pain, hypoglycemia up to hypoglycemic coma, agranulocytosis, anemia, sulfhemoglobinemia and methemoglobinemia (cyanosis, shortness of breath, heart pain), hemolytic anemia, bruising or bleeding, increased liver enzyme activity, usually without jaundice, angioedema, urticaria, hypotension, renal colic, hepatic necrosis.

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.
4 years.

Storage conditions.
Store in the original package at a temperature not more than 25 °C.
Keep out of reach of children.

Package.
100 ml are in a bottle. Each bottle is in a carton box along with a measuring cup.

Conditions of supply.
Without prescription.

Manufacturer.
LLC “KUSUM PHARM”.

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

or

Manufacturer.
LLC “GLADPHARM LLC”.

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

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