UNIDROX
600 mg film-coated tablets
Prulifloxacin

COMPOSITION
Each film-coated tablet contains:
Active substance: prulifloxacin 600 mg.
Excipients: Core: lactose monohydrate; microcrystalline cellulose; croscarmellose sodium; povidone; anhydrous colloidal silica; magnesium stearate; Coating: hypromellose; propylene glycol; titanium dioxide (E171); talc; ferric oxide (E172).

PHARMACEUTICAL FORM AND CONTENT
Film-coated tablets.
Yellow, oblong, film-coated tablets.
box of 1 × 600 mg tablet
box of 2 × 600 mg tablets
box of 5 × 600 mg tablets
box of 10 × 600 mg tablets

PHARMACOTHERAPEUTIC GROUP
Antibiotic of the fluoroquinolone class.

MARKETING AUTHORISATION HOLDER
Viale Amelia 70 - 00181 Rome

MANUFACTURER AND FINAL CONTROLLER

THERAPEUTIC INDICATIONS
Unidrox is indicated in the treatment of infections caused by susceptible organisms, in the following conditions:
- acute uncomplicated lower urinary tract infections (simple cystitis);
- complicated lower urinary tract infections;
- acute exacerbation of chronic bronchitis.
The local antibiotic susceptibility pattern should be considered in the treatment of patients with infectious diseases.

CONTRAINDICATIONS
- Hypersensitivity to prulifloxacin, other quinolone antibacterials or any of the excipients.
- Pre-pubertal children or adolescents below 18 years of age with incomplete skeletal development.
- Patients with a history of tendon diseases related to the administration of quinolones.
- Pregnancy and lactation (see “Special Warnings”).
PRECAUTIONS FOR USE
As for other quinolones, Unidrox should be used with caution in patients with CNS disorders that may predispose to seizures or lower the seizure threshold.
Preclinical studies have not shown any effect of prulifloxacin on the QTc interval. However, this possibility cannot be excluded, since this effect has been observed with drugs of the same class. Thus, in patients with hypokalaemia and hypocalcaemia or in patients who have arrhythmias, the use of quinolones should be carefully assessed, possibly combining monitoring of the QTc interval.
As after the administration of other drugs of the same class, tendonitis rarely appears. It most frequently involves the Achilles tendon and may lead to rupture of it. The risk of tendonitis and tendon rupture is increased in elderly patients and in patients on corticosteroid treatment. Patients should be advised to discontinue treatment if there are signs of tendon inflammation, myalgia, joint pain or inflammation, and to rest the affected limb(s) until the diagnosis of tendonitis has been excluded.
Treatment with antimicrobials, including quinolones, may result in the development of pseudomembranous colitis. Thus, in the event of diarrhoea following the administration of antimicrobials, it is important to consider this possibility.
Patients with latent or known defects of glucose-6-phosphate dehydrogenase activity are predisposed to haemolytic reactions when they are treated with antibacterial drugs of the quinolone class and for this reason Unidrox should be used with caution.
As reported for other quinolones, signs of rhabdomyolysis may rarely occur, in the form of myalgia, asthenia, increase in plasma CPK and myoglobin levels and a rapid deterioration of renal function. In these cases, the patient should be closely monitored and the appropriate corrective measures should be adopted, including the possible discontinuation of treatment.
This use of quinolones is sometimes associated with the appearance of crystalluria; patients on treatment with this class of products should maintain an adequate water balance in order to prevent urine concentration.
The tolerability and efficacy of Unidrox in patients with hepatic insufficiency have not been evaluated.
When prescribing antibiotic therapy, the local and/or national guidelines on the appropriate use of antibacterials should be considered.

INTERACTIONS
Concomitant treatment with cimetidine, aluminium- or magnesium-containing antacids or preparations containing iron and calcium reduces the absorption of Unidrox, so Unidrox should be administered 2 hours before or at least 4 hours after these preparations are taken.
Concomitant ingestion of prulifloxacin and milk results in a decrease in the area under the concentration-time curve (AUC) and reduces the urinary elimination of prulifloxacin, while the ingestion of food slows and reduces the peak levels.
The urinary excretion of prulifloxacin decreases when it is administered together with probenecid. The concomitant administration of fenbufen with some quinolones may result in an increase in the risk of seizures; the administration of Unidrox and fenbufen should therefore be carefully evaluated.
Quinolones may give rise to hypoglycaemia in diabetic patients taking hypoglycaemic drugs.
The concomitant administration of Unidrox and theophylline may cause a slight decrease in the clearance of theophylline, which should not have any clinical significance. Nevertheless, as for other quinolones, the monitoring of plasma theophylline levels is recommended in
patients with metabolic disorders or who have risk factors. Quinolones may increase the effects of oral anticoagulants such as warfarin and its derivatives; when these products are administered together with Unidrox, close monitoring using the prothrombin test or other reliable tests of coagulation is recommended. Preclinical data have shown that nicardipine may potentiate the phototoxicity of prulifloxacin. No clinically significant interaction has been observed during the clinical development of Unidrox following concomitant administration with other medicinal products commonly used in the treatment of patients with the diseases listed under “Therapeutic Indications.”

SPECIAL WARNINGS
Exposure to sun or ultraviolet rays may result in the appearance of phototoxicity in patients on treatment with prulifloxacin, as with other quinolones. During treatment with Unidrox, excessive exposure to sun or ultraviolet rays should be avoided; should phototoxicity occur, the treatment should be stopped. The medicinal product contains lactose; patients with rare hereditary problems of galactose intolerance, with Lapp lactase deficiency or glucose-galactose malabsorption should not take the medicinal product.

Pregnancy and lactation
There are no clinical data on the use of prulifloxacin during confirmed pregnancy. Animal studies did not show teratogenicity. Other toxic effects on reproduction were seen only in case of maternal toxicity. However, in rats, prulifloxacin was noted to cross the placenta and pass into maternal milk in large quantities. As with other quinolones, prulifloxacin has been shown to cause arthropathy in young animals and thus its use during pregnancy and lactation is contraindicated.

Driving and use of machines
Quinolones may cause dizziness and confusion; the patient should therefore know how he/she reacts to the treatment before driving or using machines or starting activities that require attention and coordination.

Keep the product out the reach and sight of children.

DOSE, METHOD AND TIME OF ADMINISTRATION
For adults only, the indicative dosage is as follows:

- patients with acute uncomplicated lower urinary tract infections (simple cystitis): one 600 mg tablet is sufficient;
- patients with complicated lower urinary tract infections: one 600 mg tablet once daily for up to a maximum of 10 days of treatment.
- patients with acute exacerbation of bronchitis: one 600 mg tablet once daily for up to a maximum of 10 days of treatment.

In case of complicated lower urinary tract infections and acute exacerbation of chronic bronchitis, the length of treatment depends on the severity of the disease and the patient's clinical outcome and should in any case be continued for at least 48-72 hours after remission/disappearance of symptoms.
Unidrox tablets should be swallowed whole with water and should be taken considering food intake (see "Interactions"). Because of the lack of specific studies, it is not possible to determine the dosage in patients with renal insufficiency (patients with creatinine clearance < 60 ml/min) and in patients with hepatic insufficiency. Thus, in these patients, monitoring of the plasma levels of the drug is the most reliable method for adjustment of the dosage.

OVERDOSE
In case of acute overdose, the stomach should be emptied by inducing vomiting or undertaking gastric lavage, the patient should be carefully monitored and treated using symptomatic therapy.

UNDESIRABLE EFFECTS
The undesirable effects listed below are based on the clinical studies conducted with Unidrox. The majority of the adverse events were of mild or moderate severity.

The following frequencies were used: 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) and very rare (<1/10,000 including isolated reports).

- General disorders and administration site conditions – Rare: fever
- Nervous system disorders – Uncommon: headache, dizziness. Rare: taste disturbances.
- Psychiatric disorders - Rare: sleep disorders, somnolence, confusion.
- Ear and labyrinth disorders – Rare: impaired hearing.
- Eye disorders – Rare: ocular hyperaemia
- Gastrointestinal disorders - Common (only in case of prolonged treatment): epigastralgia, nausea. Uncommon: diarrhoea, epigastralgia, nausea, gastritis and vomiting. Rare: abdominal pain, gastrointestinal disorders, angular stomatitis, dyspepsia, flatulence, indigestion, oral cavity disorders, oral moniliasis, glossitis, gastric dilation. The frequency of epigastralgia and nausea may be higher in case of prolonged treatments.
- Musculoskeletal and connective tissue disorders – Rare: muscle spasms, rhabdomyolysis.
- Skin and subcutaneous tissue disorders – Uncommon: pruritus, skin rash. Rare: facial eczema, phototoxicity and urticaria.
- Vascular disorders – Rare: hot flushes.
- Investigations – Rare: increase in γ-GT, increase in bilirubin.
- Metabolism and nutrition disorders – Uncommon: anorexia.

The following adverse reactions were reported very rarely (<1/10,000): anaphylactic/anaphylactoid reaction, Steven Johnson syndrome, hypoglycaemia, hypoaesthesia, drug-induced dermatitis. Treatment with Unidrox may be associated with asymptomatic crystalluria without a change in the creatinine levels, changes in liver function tests and eosinophilia. In the observed cases, these changes were asymptomatic and transient.

During treatment with Unidrox, the appearance of adverse reactions and changes in laboratory parameters not mentioned above but reported for other quinolones, cannot be excluded.

Post-marketing pharmacovigilance data on prulifloxacin show sporadic reports of tendon disorders (see "Precautions for use").
The risk of undesirable effects is reduced by following the instructions contained in the package leaflet. It is important to inform the doctor or pharmacist of the appearance of any undesirable effect even though it is not described in the package leaflet.

EXPIRY AND STORAGE
Store below 30°C.
Store in the original package.
Caution: do not use the product after the expiry date shown on the package.

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