This package insert is continually updated: please read carefully before using a new pack!

Uro Tarivid® 100

Active ingredient: Ofloxacin

Composition
Each film-coated tablet contains 100 mg ofloxacin as active ingredient.
Excipients: Lactose, maize starch, hyprolose, carmellose, magnesium stearate, titanium dioxide, hypromellose, macrogol 8000, talc.

Properties
Ofloxacin, the active ingredient of Uro Tarivid 100, is a bactericidal quinolone antibiotic.

Indications
Uro Tarivid 100 is indicated for the treatment of the following bacterial infections, if these are due to ofloxacin-sensitive pathogens: **infections of the urinary tract, such as, e.g., uncomplicated infections of the bladder (cystitis), and of the urethra (gonococcal urethritis).**
When used in higher doses and over extended periods of treatment, ofloxacin is also suited for the treatment of the following bacterial infections:
- infections of the kidney and of the genital organs.
- acute, chronic, or recurrent lower respiratory tract infections (bronchitis), especially if caused by Haemophilus influenzae or other Gram-negative or multi-restistant pathogens, as well as by Staphylococcus aureus.
- pneumonia, especially if caused by problem pathogens such as Escherichia coli, Klebsiella, Enterobacter, Proteus, Pseudomonas, Legionella, or Staphylococcus. Since in outpatients pneumococci are the most frequent pathogens responsible for pneumonia, ofloxacin is not the treatment of first choice in these patients.
- chronic and recurrent infections of the ear, nose, and throat, especially if caused by Gram-negative pathogens including Pseudomonas, or by Staphylococcus. However, ofloxacin is in general not indicated for the treatment of acute tonsillitis caused by beta-haemolytic streptococci.
- infections of soft tissues and skin.
- abdominal infections including infections in the pelvis minor and bacterial enteritis.

Antibacterial spectrum
The following microorganisms may be regarded as susceptible: Staphylococcus aureus (incl. methicillin-resistant staph.), Staphylococcus epidermidis, Neisseria gonorrhoeae, Neisseria meningitidis, Escherichia coli, Citrobacter, Klebsiella, Enterobacter, Hafnia, Proteus (indole-negative and indole-positive strains), Salmonella, Shigella, Yersinia enterocolitica, Campylobacter jejuni, Aeromonas, Plesiomonas, Vibrio cholerae, Vibrio parahaemolyticus, Haemophilus influenzae, Chlamydiae, Legionella.
The following microorganisms vary in their susceptibility: Enterococci, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus viridans, Serratia marcescens, Pseudomonas aeruginosa, Acinetobacter, Mycoplasma hominis, Mycoplasma pneumoniae, Mycobacterium tuberculosis, and Mycobacterium fortuitum.
The following microorganisms are usually restistant to ofloxacin: Ureaplasma urealyticum, Nocardia asteroides, anaerobes (e.g. Bacteroides spp., Peptococcus, Peptostreptococcus, Eubacterium spp., Fusobacterium spp., Clostridium difficile).
Ofloxacin is not effective against Treponema pallidum.

Contraindications
Uro Tarivid 100 must not be used
- in patients hypersensitive to ofloxacin, other quinolones or any of the excipients (see under "Composition").
- in epileptics as well as in patients with a lowered cerebral seizure threshold due to pre-existing central nervous system lesions, e.g. after cerebrocranial injuries, inflammations in the region of the CNS, or stroke (increased risk of convulsive seizures).
- in children or adolescents in the growth phase, during pregnancy or in breast-feeding women (since – judging from animal experiments – risk of damage to the cartilage of joints in the growing organism cannot be entirely excluded).

Special warnings and precautions
Patients with a history of severe adverse reactions (e.g., inflammation of a tendon [tendinitis], severe neurological reactions) to other quinolones may be at increased risk of similar reactions to ofloxacin.
Administration of antibiotics, especially if prolonged, may lead to the proliferation of resistant microorganisms. The patient's condition must therefore be checked at regular intervals. If a secondary infection occurs, appropriate measures must be taken.
Patients undergoing treatment with Uro Tarivid 100 are advised not to expose themselves unnecessarily to strong sunlight and to avoid UV rays (sunray lamp, solarium). Otherwise, skin and nail reactions may occur (see under "Adverse effects").
Some adverse effects (see under "Adverse effects") may impair the ability to concentrate and react, and, therefore, constitute a risk in situations where these abilities are of particular importance (e.g. driving a car or operating machinery).

Adverse effects
Gastrointestinal tract: During treatment with Uro Tarivid 100, stomach upsets, abdominal pain, loss of appetite, nausea, vomiting, or diarrhoea may occur.
Diarrhoea may sometimes be s symptom of enterocolitis, which may, in some cases, be accompanied by blood in stools. A particular form of enterocolitis that can occur with antibiotics is pseudomembranous colitis (in most cases due to Clostridium difficile). This possibility must be considered in patients in whom severe, persistent diarrhoea occurs during treatment or in the initial weeks thereafter. Even if pseudomembranous colitis is only suspected, administration of Uro Tarivid 100 must be halted immediately. This type of colitis requires immediate and appropriate treatment by a physician. Drugs that inhibit intestinal motility (peristalsis) must not be taken in such cases.
Liver: Rarely, an increase in serum levels of hepatic enzymes or impairment of liver function with an increase in serum bilirubin may occur. Very rarely, jaundice due to impairment of bile flow (cholestatic jaundice), inflammation of the liver (hepatitis) or severe liver damage may develop.
Nervous system: Headache, dizziness, sleep disorders, agitation and confusion may occur. In rare cases, drowsiness, unsteadiness of galt and tremor (due to disorders of muscular coordination), extrapyramidal symptoms (increased or decreased muscle tone, involuntary movements of the face and body, tremor at rest, a decrease in spontaneous movements or slowness in initiating movements), convulsions, numbness and tingling (paraesthesia or hypaesthesia) may occur. Rarely, visual disorders such as blurred vision, double vision, and abnormal colour vision, disorders of taste and smell (including loss of taste and smell) and of equilibrium may develop. Noises in the ears (tinnitus) and disorders of hearing (in exceptional cases even loss of hearing) are rare with ofloxacin.
In very rare cases, vivid dreaming (sometimes amounting to nightmares) and psychotic reactions such as anxiety, depression, and hallucinations may occur. Certain psychotic reactions may, in some cases, lead to self-endangering behaviour.
Such reactions may occur even after the first dose. In the event of such reactions, Uro Tarivid 100 must be discontinued immediately.
Cardiovasular system: Ingestion of Uro Tarivid 100 may be followed by acceleration of the heart beat (lachycardia) and a temporary decrease in blood pressure. In rare cases, as a consequence of a pronounced drop in blood pressure, circulatory collapse may occur.

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Blood: Very rarely, a reduction in the numbers of both red and white blood cells (this can include the absence of certain white blood cells) and/or of platelets (anaemia, leucopenia including agranulocytosis, thrombopenia, pancytopenia) may occur. In some cases only, these changes result from reduced new cell formation in the bone marrow (bone-marrow depression). Very rarely, a reduction in the number of red blood cells due to increased destruction (haemolytic anaemia) may develop.

Kidneys: Rarely, impairment of renal function with, e.g., an increase in serum creatinine may develop, as may – in isolated cases – acute inflammation of the kidney (interstitial nephritis). These reactions may sometimes progress to acute renal failure.

Skin, mucous membranes and other reactions: Cutaneous and mucosal reactions such as itching and skin rashes (in exceptional cases, with blisters or small pus-filled vesicles) may develop. In very rare cases reddening of the skin accompanied by heat sensations, severe skin reactions (erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome), and inflammation of the vessels (vasculitis) may occur. Generally, vasculitis can manifest itself in the form of tiny red dots caused by bleeding under the skin (petechiae), of blood-filled blisters (haemorrhagic bullae), and of small nodules with crust formation, but can also lead to skin lesions including irreversible damage (necrosis) in exceptional cases. Vasculitis may also involve internal organs.
Hypersensitivity to light may develop in very rare cases. This may resemble severe sunburn and in some cases also involve the nails (discolouration, loosening).
Fever, eosinophilia, and allergic inflammation of the lungs (allergic pneumonitis) may develop in very rare cases.
Anaphylactic or anaphylactoid reactions (rapidly developing allergic or allergy-like hypersensitivity reactions) may occur in very rare instances, but sometimes even after the first dose. These may manifest themselves, for example, in a rise in blood pressure, burning sensations in the eyes, tickling cough, and nasal catarrh. However, they may also be accompanied by swelling of the skin and mucous membranes (angio-oedema), for example, involving the face, tongue, and larynx (symptoms: hoarseness, difficulty in breathing). In the most serious cases, severe respiratory distress (also caused by bronchial spasm) or circulatory collapse (shock) may develop. In the event of such reactions, treatment with Uro Tarivid 100 must be halted immediately and medical treatment (e.g. for shock) initiated.
Sweating may occur. In very rare cases, muscular complaints such as pain or weakness (of special significance in, e.g., patients with myasthenia gravis) may occur. In isolated cases, these may be symptoms of a muscle disease (rhabdomyolysis) entailing destruction of muscle tissue, which, in some cases, can lead to muscular atrophy and acute renal failure. Very rarely, joint and tendon discomfort (e.g. pain) may occur.
In very rare cases, inflammation of tendons (tendinitis) and rupture (e.g. of the Achilles tendon) may occur in isolated instances during treatment with quinolones. Such events have been observed particularly in patients treated concurrently with corticosteroids. If tendinitis is suspected, treatment with Uro Tarivid 100 must be halted immediately, and appropriate treatment must be initiated for the affected tendon.
The possibility cannot be ruled out that ofloxacin may trigger an attack of porphyria in predisposed patients.
Excessive rises or falls in the blood-sugar level (hyper- or hypoglycaemia) may occur in isolated cases.
Administration of antibiotics, especially if prolonged, may lead to the proliferation of resistant microorganisms (see also under "Special warnings and precautions").
Except in very rare instances (isolated cases of, e.g., smell, taste and hearing disorders), the adverse effects observed subsided after discontinuation of Uro Tarivid 100.
Please consult a physician if you notice any of the adverse effects listed in this package insert or any other undesired effects or unexpected changes.
Since some adverse drug effects (for example, pseudomembranous colitis, some changes in blood picture, severe anaphylactic or anaphylactoid reactions, severe skin reactions) may under certain circumstances become life-threatening, it is essential that, if sudden or severe reactions do occur, you inform a physician at once and on no account continue taking the drug without a physician's express guidance.

Interactions
If certain medicines against hyperacidity of the stomach (mineral antacids), sucralfate, or iron preparations are taken concurrently, an attenuation of the effect of Uro Tarivid 100 must be taken into account. For this reason, the Uro Tarivid 100 tablets must be taken about 2 hours before taking such preparations.
There are indications of a pronounced lowering of the cerebral seizure threshold when quinolones are given concurrently with other drugs that lower the seizure threshold (e.g. theophylline) or with certain nonsteroidal anti-inflammatory drugs (e.g. fenbufen).
Uro Tarivid 100 may cause a slight increase in serum concentrations of glibenclamide administered concurrently; patients treated concomitantly with Uro Tarivid 100 and glibenclamide should therefore be particularly closely monitored.
Particularly in high-dose therapy, mutual impairment of excretion and an increase in serum levels must be considered when quinolones are administered together with other drugs that also undergo renal tubular secretion (such as probenecid, cimetidine, furosemide, or methotrexate).
In patients who are treated with quinolones, an increase in the effect of coumarin derivatives cannot be ruled out. Patients undergoing concurrent treatment with coumarin derivatives should therefore be carefully monitored.
Interference with laboratory tests
Determination of opiates or porphyrins in urine may give false-positive results during treatment with Uro Tarivid 100.

Dosage and administration
The usual dosage for the treatment of uncomplicated infections of the lower urinary tract is 2 tablets daily.
Dosage in patients with impaired renal function: In patients with impaired renal function, the following dosages are recommended: The initial dose is the same as for patients with normal renal function, whereas the maintenance dose should be reduced as follows:

Creatinine clearance	Maintenance dose
50–20 ml/min	1–2 tablets every 24 hours
< 20 ml/min	1 tablet every 24 hours

Dosage in patients with impaired liver function: The excretion of ofloxacin may be reduced in patients with severe impairment of liver function (e.g. cirrhosis with ascites). A maximum daily dose of 400 mg ofloxacin should therefore not be exceeded.
Duration of treatment
The duration of treatment depends on the response of the causative organism and on the clinical picture.
For uncomplicated infections of the lower urinary tract, 3 days' treatment is usually sufficient; in women, a single treatment with one tablet Uro Tarivid 100 is usually sufficient.
Until further experience is available, the duration of treatment should not exceed 2 months.
Administration
Uro Tarivid 100 tablets should be swallowed **without chewing** with sufficient amounts of liquid (approx. ½ glass). They may be taken on an empty stomach or with meals. It is important that the tablets be taken at approximately equal intervals.

Expiry date
Do not use later than the date of expiry.

Keep medicament out of the reach of children.

Presentation
6 scored film-coated tablets

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