TAVANIC® 500 mg film-coated tablets Abbreviated Prescribing Information

1. NAME AND PRESENTATION: One Tavanic 500 mg film-coated tablet, contains 500 mg of levofloxacin as levofloxacin hemihydrate. **2. THERAPEUTIC INDICATIONS**: Acute pyelonephritis and complicated urinary tract infections, chronic bacterial prostatitis, pulmonary anthrax: for prophylaxis after exposure and as curative treatment, acute bacterial sinusitis, acute exacerbations of chronic obstructive pulmonary disease including bronchitis, community-acquired pneumonia, complicated skin and soft tissue infections, uncomplicated cystitis. Tavanic may also be used to continue treatment in patients who improved during initial treatment with intravenous levofloxacin. **3. POSOLOGY AND METHOD OF ADMINISTRATION**: Tavanic tablets are administered once or twice daily. The dosage depends on the type and severity of the infection and the sensitivity of the suspected causative pathogen. Tavanic tablets may also be used to continue treatment in patients who improved during initial treatment with intravenous levofloxacin; due to the bioequivalence of the parenteral and oral forms, the same dosage can be used. Acute bacterial sinusitis: 500 mg Once daily (10-14 days). Acute bacterial exacerbations of chronic obstructive pulmonary disease including bronchitis: 500 mg Once daily (7-10 days). Community -acquired pneumonia: 500mg once or twice daily (7-14 days). Acute pyelonephritis: 500 mg once daily (7 to 10 days). Complicated urinary tract infections: 500 mg once daily (7 to 14 days). Uncomplicated cystitis: 250 mg once daily (3 days). Chronic bacterial prostatitis: 500 mg once daily (28 days), Complicated skin and soft tissue Infections: 500 mg once or twice daily (7-14 days). Pulmonary anthrax: 500 mg once daily (8 weeks). **4. CONTRA-INDICATIONS:** In patients with hypersensitivity to levofloxacin or other quinolones or any of the excipients listed. In patients with epilepsy. In patients with a history of tendon discomfort after previous use of fluoroquinolones. In children and adolescents in the growth phase. During ppregnancy and breastfeeding. **5. SPECIAL WARNINGS AND PRECAUTIONS FOR USE**: Methicillin-resistant *S. aureus* is likely to have co-resistance to fluoroquinolones (including levofloxacin). Therefore, in the case of known or suspected MRSA infection, levofloxacin is not recommended for treatment unless laboratory results confirm susceptibility of the pathogen to levofloxacin (and antibiotics commonly recommended for the treatment of MRSA are not regarded as indicated). Levofloxacin can be used to treat acute bacterial sinusitis or acute exacerbation of chronic bronchitis if these infections have been professionally diagnosed. The resistance of *E. coli*, the most common pathogen of urinary tract infections, to fluoroquinolones varies within the European Union. Physicians should consider the local prevalence of the resistance of *E.coli* to fluoroquinolones when prescribing. In very rare cases, persistent adverse effects (lasting months or years) affecting quality of life and potentially irreversible serious adverse reactions affecting various body systems (motor system, nerves, psyche and sensory organs) – sometimes multiple systems at the same time – have been reported in patients receiving quinolones and fluoroquinolones, independent of age and pre-existing risk factors. Levofloxacin should be discontinued immediately at the first signs or symptoms of a serious adverse reaction, and patients should be instructed to consult their prescribing physician. Tendinitis and tendon rupture. Cases of myoclonus have been reported in patients receiving levofloxacin. Clostridium difficile-associated disease, Patients prone to seizures, Patients with glucose-6-phosphate dehydrogenase deficiency, Patients with renal impairment, Hypersensitivity reactions, Severe cutaneous adverse reactions, Dysglycaemia, Prevention of photosensitization, Patients treated with Vitamin K antagonists, Psychotic reactions, QT interval prolongation, Peripheral neuropathy, Hepatobiliary disorders, Exacerbation of myasthenia gravis, Visual Disturbances, Superinfection, Interference with laboratory results, *Aortic aneurysm, aortic dissection and heart valve regurgitation, patient with acute pancreatitis, patient with blood disorders, and this product is a sodium free.* For more information always Refer to Full SMPC. **6. DRUG INTERACTIONS**: *Iron salts, zinc salts, antacids containing magnesium or aluminium, didanosine*, sucralfate, theophylline, fenbufen or similar NSAID, probenecid and cimetidine, cyclosporine, vitamin K antagonists, Medicinal products known to prolong the QT interval, see full SmPC. **7. PREGNANCY AND LACTATION**: *Pregnancy:* There are limited amount of data from the use of levofloxacin in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Nevertheless, levofloxacin must not be used in pregnant women. *Breast feeding*: Tavanic is contraindicated during breast-feeding. There is insufficient information on the excretion of levofloxacin in human milk. *Fertility*: Levofloxacin did not cause any impairment in fertility or productivity in rats. **8. EFFECTS ON ABILITY TO DRIVE and use machines:** Tavanic has minor or moderate influence on the ability to drive and use machines. **9. UNDESIRABLE EFFECTS**: Common side effects: Psychiatric disorders: difficulty sleeping(insomnia). Nervous system disorder: headaches, giddiness. Vascular disorders: only after IV application (phlebitis). Gastrointestinal: diarrhea, vomiting, nausea. Hepatobiliary disorders: elevated liver enzyme ALTand AST. General disorders and administration site conditions: pain, redness of the infusion site. For uncommon, rare, and very rare side effects see full SmPC **10. OVERDOSAGE**: NS effects (including confusion, seizures, myoclonia, hallucinations, and tremor) were observed after market introduction. In case of overdose, symptomatic treatment should be initiated. ECG monitoring should be performed due to the potential for QT interval prolongation to occur. Antacids can be used to protect the gastric mucosa. **11. DATE OF REVISION:** July 2024. **12. MARKETING AUTHORIZATION HOLDER:** Sanofi-Aventis Deutschland GmbH

To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:
Levant.Pharmacovigilance@sanofi.com for adverse events
Levant.medinfo@sanofi.com for medical inquiries
Quality.Levant@sanofi.com for product technical complaints
Before prescribing, refer to the full Summary of Product Characteristics (SmPC).

MAT-IQ-2600058-1.0-04/2026