Tavanic Infusion ® Abridged Prescribing Information:

1-NAME & PRESENTATION: Tavanic 250 mg Film tablet and Tavanic 500 mg Film tablet

2. Therapeutic INDICATIONS:

− acute bacterial sinusitis,

− acute exacerbation of chronic bronchitis,

− community-acquired pneumonia,

− complicated skin and soft-tissue infections.

For the above-mentioned infections, Tavanic should be used only when antibiotics usually recommended for the initial treatment of these infections are not considered to be indicated.

− pyelonephritis and complicated urinary tract infections (see section 4.4),

− chronic bacterial prostatitis,

− uncomplicated cystitis (see section 4.4),

− inhalation anthrax: for post-exposure prophylaxis and as curative treatment (see section 4.4).

Tavanic can also be used to continue a course of treatment in patients who have shown improvement during initial treatment with intravenous levofloxacin.

Consideration should be given to the official recommendations on the appropriate use of antibiotics.

3. DOSAGE & POSOLOGY OF ADMINISTRATION: Tavanic film-coated tablets are administered once or twice daily. The dosage depends on the type and severity of the infection and the susceptibility of the presumed causative pathogen.

Indication	**Daily dosage** (according to severity)	**Duration of treatment**[1] (according to severity)
Community-acquiredpneumonia	500 mg once or twice daily	7 – 14 days
Pyelonephritis	500 mg once daily	7 – 10 days
Complicated urinary tractinfections	500 mg once daily	7 – 14 days
Chronic bacterial prostatitis	500 mg once daily	28 days
Complicated skin and softtissue infections	500 mg once or twice daily	7 – 14 days
Inhalation anthrax	500 mg once daily	8 weeks

Tavanic tablets can also be used to continue a course of treatment in patients who have shown improvement during initial treatment with intravenous levofloxacin. Given the bioequivalence of the parenteral and oral forms, the same dose can be used.

4. SPECIAL POPULATION: Renal impairment Due to the hydrochlorothiazide component, CoAprovel is not recommended for patients with severe renal dysfunction (creatinine clearance < 30 ml/min). Loop diuretics are preferred to thiazides in this population. No dosage adjustment is necessary in patients with renal impairment whose renal creatinine clearance is ≥ 30 ml/min. Hepatic impairment CoAprovel is not indicated in patients with severe hepatic impairment. Thiazides should be used with caution in patients with impaired hepatic function. No dosage adjustment of CoAprovel is necessary in patients with mild to moderate hepatic impairment

4. CONTRA-INDICATIONS: Levofloxacin solution for infusion must not be used: in patients with hypersensitivity to levofloxacin or other quinolones, or to any of the excipients, in patients with epilepsy, in patients with a known history of tendon disorders after previous fluoroquinolone use, in children and growing adolescents, during pregnancy, in breast-feeding women.

5-WARNINGS & PRECAUTIONS: The use of Levofloxacin should be avoided in patients who have experienced serious adverse reactions in the past when using quinolone or fluoroquinolone containing products (see section 4.8). Treatment of these

patients with Levofloxacin should only be initiated in the absence of alternative treatment options and after careful benefit/risk assessment.

6. INTERACTIONS: Theophylline, fenbufen or similar non- steroidal anti-inflammatory drugs, Probenecid and cimetidine, Levofloxacin should be used with caution when co-administering medicinal products that affect tubular renal secretion, e.g. probenecid and cimetidine. This particularly applies to patients with renal insufficiency.

7. PREGNANCY AND LACTATION: There are only few data on the use of levofloxacin in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). Nevertheless, levofloxacin must not be used in pregnant women, as studies in humans are lacking and experimental data in animals indicate the risk of possible damage by fluoroquinolones to the cartilage tissue of weight-bearing joints in growing animals, Breast-feeding Tavanic is contraindicated in breast-feeding women. There is insufficient information on the excretion of levofloxacin in human breast milk.

8. EFFECTS ON ABILITY TO DRIVE: Some undesirable effects (e.g. light- headedness/dizziness, drowsiness, visual disturbances) may impair the patient's ability to concentrate and react and may therefore constitute a risk in situations where these abilities are of special importance (e.g. driving a car or using machines).

9. ADVERSE REACTIONS: Nightmares , vertigo, dyspnea, tremor, anorexia , headache, phlebitis, diarrhea, vomiting , elevated liver enzymes .

10.Overdose: According to toxicity studies in animals or clinical pharmacology studies with supratherapeutic doses, the most important symptoms to be expected following acute overdose of Tavanic solution for infusion are central nervous symptoms (confusion, light- headedness, impairment of consciousness and seizures) and prolongation of the QT interval..

11.Pharmacodynamics: Pharmacotherapeutic group: quinolone antibacterials, fluoroquinolones, ATC code: J01MA12.

Levofloxacin is a synthetic antibiotic of the fluoroquinolone group. It is the S (-) enantiomer of the racemate ofloxacin. Mechanism of action As a fluoroquinolone antibiotic, levofloxacin acts on the DNA-DNA gyrase complex

12. MARKETING AUTHORIZATION HOLDER: Sanofi-aventis Deutschland GmbH, D - 65926 Frankfurt am Main. Abbreviated Prescribing Information based on the EU SmPC as of March 2016 . Always refer to the full Summary of Product Characteristics (SmPC) before prescribing.