Northern Ireland Prescribing Information can be found on Page 2

PRESCRIBING INFORMATION (Great Britain)

▼Quofenix (delafloxacin) 300 mg powder for concentrate for solution for infusion and ▼Quofenix (delafloxacin) 450 mg tablets

Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

Presentation: Powder for concentrate for solution for infusion (powder for concentrate). Oblong biconvex tablets.

Use: Adult patients with acute bacterial skin and skin structure infections (ABSSSI), or community-acquired pneumonia (CAP). Due to serious adverse reaction risks, only prescribe when other antibiotics commonly recommended for these infections are inappropriate [see SmPC].

Dosage and administration: Infusion: 300 mg every 12 hours administered over 60 minutes by intravenous infusion. Switch to 450 mg tablet orally every 12 hours is possible at the physician's discretion. Tablets: 450 mg every 12 hours with or without food. Duration of treatment: 5 to 14 days for ABSSSI and 5 to 10 days for CAP. No adjustment for age required, nor for hepatic impairment. Renal impairment: Not recommended in End Stage Renal Disease (ESRD). *Infusion:* No dosage adjustment for mild to moderate renal impairment. Severe renal impairment (CrCl of <30 mL/min) decrease dose to 200 mg every 12 hours; alternatively give 450 mg delafloxacin orally every 12 hours. *Tablets:* No dose adjustment necessary in patients with mild to severe renal impairment.

Contraindications: Hypersensitivity to the active substance, any of the excipients, or to any fluoroquinolone/quinolone. History of tendon disorders related to fluoroquinolones. Pregnancy, women of childbearing potential not using contraception, breast-feeding. Children or adolescents below 18 years of age.

Warnings and Precautions: Patients who have previously experienced serious adverse reactions using quinolone/fluoroquinolones: avoid use. Treatment of these patients should only be initiated in the absence of alternatives and after careful risk/benefit assessment. Contraception: effective contraception must be used during treatment of sexually mature women. Aortic aneurysm and dissection, and heart valve regurgitation/incompetence: epidemiology studies report an increased risk of aortic aneurysm and dissection, particularly in elderly patients, and of aortic and mitral valve regurgitation after intake of fluoroquinolones. Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones. Therefore, fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease or congenital heart valve disease, or in patients diagnosed with preexisting aortic aneurysm and/or aortic dissection or heart valve disease, or in presence of other risk factors or conditions predisposing for both aortic aneurysm and dissection and heart valve regurgitation/incompetence. The risk of aortic aneurysm and dissection, and their rupture may also be increased in patients treated concurrently with systemic corticosteroids. In case of sudden abdominal, chest or back pain, patients should be advised to immediately consult a physician in an emergency department. Patients should be advised to seek immediate medical attention in case of acute dyspnoea, new onset of heart palpitations, or development of oedema of the abdomen or lower extremities. Tendinitis and tendon rupture: this may occur within 48 hours of starting treatment with quinolones/fluoroquinolones up to several months after discontinuation. Risk increased in older patients, renal impairment, solid organ transplants, and those treated concurrently with corticosteroids. Therefore, avoid comcomitant use with corticosteroids. Discontinue at first sign of tendinitis. Peripheral neuropathy: sensory or sensimotor polyneuropathy resulting in paraesthesia, hypaesthesia, dysaesthesia or weakness reported with quinolones/fluoroquinolones. CNS effects: Fluoroquinolones have been associated with increased risk of central nervous system (CNS) reactions, including convulsions, increased intracranial pressure and toxic psychosis. Fluoroquinolones may also cause CNS reactions: nervousness, agitation, insomnia, anxiety, nightmares, paranoia, dizziness, confusion, tremors, hallucinations, depression and suicidal thoughts/ acts which may occur following first dose. If these reactions occur, discontinue delafloxacin immediately and institute appropriate measures. Myasthenia gravis: fluoroquinolones may exacerbate muscle weakness in myasthenia gravis. *Clostridioides difficile*-associated disease has been reported with systemic antibacterial medicinal products. Medicinal products inhibiting peristalsis contraindicated if *Clostridioides difficile*-associated disease suspected. Hypersensitivity reactions: serious and occasionally fatal reactions have been reported with fluoroquinolones. Discontinue immediately if an anaphylactic reaction occurs and institute appropriate therapy. Renal impairment: Not recommended in ESRD. *Infusion:* Dose adjustment needed in patients with severe renal impairment. Safety and efficacy of dose adjustment guidance in these patients has not been clinically evaluated and is based on pharmacokinetic modelling data. Only use in such patients when expected clinical benefit outweighs potential risk. Clinical response to treatment and renal function should be closely monitored in these patients. Accumulation of the intravenous vehicle sulfobutylbetadex sodium occurs in patients with moderate to severe renal impairment; therefore serum creatinine levels should be monitored closely in these patients, and, if increases occur, consider switching to tablets, 450 mg every 12 hours. *Tablets:* Safety and efficacy in patients with severe renal impairment has not been clinically evaluated and is based on pharmacokinetic modelling data. Only use in such patients when the expected clinical benefit outweighs the potential risk. Clinical response to treatment and renal function should be closely monitored in these patients. Administration in patients with severe renal impairment and low body weight may lead to increased systemic exposures. Limitations of clinical data: trials in ABSSSI included cellulitis/erysipelas, abscesses and wound infections only. Other skin infections not studied. In the CAP study population 90.7% of patients had a CURB-65 score of ≤2. However 69.3% of patients were PORT class III, and 30.7% of patients had PORT scores >III. Prolonged, disabling and potenitally irreversible serious adverse drug reactions (ADR): cases of such reactions affecting different, sometimes multiple, body systems reported with quinolones/fluoroquinolones irrespective of age and pre-existing risk factors. Discontinue immediately at the first signs of any serious ADRs. Superinfection: fluoroquinolone non-susceptible microorganisms may result in superinfection. Dysglycaemia: as with all quinolones, blood glucose disturbances, including hypoglycaemia and hyperglycaemia have been reported, usually in diabetic patients receiving concomitant oral hypoglycaemic agent or insulin. Serious bullous skin reactions: Stevens-Johnson syndrome, toxic epidermal necrolysis, reported with other fluoroquinolones. Glucose-6-phosphate dehydrogenase deficiency: caution in patients with history or family history of G6PD deficiency. Sodium content: powder for infusion and tablets contain sodium.

Interactions: Chelation active substance: antacids, sucralfate, metal cations, multivitamins, didanosine. Tablets: Take tablets at least 2 hours before or 6 hours after these agents. Infusion: Do not co-administer infusion with any solution containing multivalent cations, e.g. magnesium, through the same intravenous line.

Pregnancy and lactation: Contraindicated during pregnancy and in women of childbearing potential not using contraception. Breast-feeding is contraindicated.

Side-effects: as reported in phase 2/3 studies. Common: most frequently reported were diarrhoea, nausea, and hypertransaminasaemia. Other common reactions were vomiting, headache, pruritis, fungal infection and, with IV dosing only, infusion site reaction. Uncommon: *Clostridioides difficile* infection, hypersensitivity, hyperglycaemia, decreased appetite, insomnia, peripheral neuropathy, dizziness, dysgeusia, blurred vision, palpitations, hypertension, hypotension, flushing, dyspnoea, stomatitis, abdominal pain, dyspepsia, dry mouth, flatulence, constipation, blood alkaline phosphatase increased, allergic dermatitis, urticaria, rash, hyperhidrosis, arthralgia, myalgia, tendonitis, musculoskeletal pain, muscle weakness, blood creatine phosphokinase increased, renal impairment, pyrexia, local swelling, fatigue. Rare: urinary tract infection, sinusitis, thrombocytopenia, neutropenia, international normalised ratio increased, seasonal allergy, hypoglycaemia, hyperuricaemia, hypokalaemia, blood potassium increased, auditory hallucinations, anxiety, abnormal dreams, confusional state, presyncope, somnolence, dry eye, vertigo, tinnitus, vestibular disorder, sinus tachycardia, bradycardia, deep vein thrombosis, phlebitis, cough, dry throat, erosive gastritis, gastro-oesophageal reflux disease, oral paraesthesia, oral hypoaesthesia, glossodynia, discoloured faeces, blood albumin decreased, gammaglutamyltransferase increased, alopecia, cold sweats, night sweats, reactive arthritis, myositis, muscle spasm, haematuria, crystal urine, peripheral oedema, chills, medical device complications and wound complications. Cases of prolonged, disabling and potentially irreversible serious drug reactions affecting several, sometimes multiple, system organ classes and senses reported with use of quinolones/fluoroquinolones in some cases irrespective of pre-existing risk factors. Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones. Refer to the SmPC for more detail.

Package quantities and price: 300 mg Powder for concentrate for solution for infusion: 10 vials £615.00; 450 mg Tablets: 10 tablets £615.00.

Legal category: POM.

Marketing Authorisation Holder: A. Menarini Industrie Farmaceutiche Riunite s.r.l. ViaSette Santi 3, 50131 Florence, Italy.

Marketing Authorisation Number: PLGB 10649/0009 and PLGB 10649/0010.

Marketed by: A. Menarini Farmaceutica Internazionale SRL. Menarini House, MercuryPark, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH. Further information is available on request to A. Menarini Farmaceutica Internazionale SRL, or may be found in the SmPC.

Last revised: January 2024

▼This medicinal product is subject to additional monitoring.
Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no. 0800 085 8678 or email: menarini@medinformation.co.uk

PP-QUO-UK-0266 January 2024

Great Britain Prescribing Information can be found on Page 1

PRESCRIBING INFORMATION (Northern Ireland)

▼Quofenix (delafloxacin) 300 mg powder for concentrate for solution for infusion and ▼Quofenix (delafloxacin) 450 mg tablets

Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

Presentation: Powder for concentrate for solution for infusion (powder for concentrate). Oblong biconvex tablets.

Use: Adults: Treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired pneumonia (CAP) when considered inappropriate to use other antibacterial agents commonly recommended for initial treatment of these infections.

Dosage and administration: Infusion: 300 mg every 12 hours administered over 60 minutes by intravenous infusion. Switch to 450 mg tablet orally every 12 hours is possible at the physician's discretion. Tablets: 450 mg every 12 hours with or without food. Duration of treatment: 5 to 14 days for ABSSSI and 5 to 10 days for CAP. No adjustment for age required, nor for hepatic impairment. Renal impairment: Not recommended in End Stage Renal Disease (ESRD). *Infusion:* No dosage adjustment for mild to moderate renal impairment. Severe renal impairment (CrCl of <30 mL/min) decrease dose to 200 mg every 12 hours; alternatively give 450 mg delafloxacin orally every 12 hours. *Tablets:* No dose adjustment necessary in patients with mild to severe renal impairment.

Contraindications: Hypersensitivity to the active substance, any of the excipients, or to any fluoroquinolone/quinolone. History of tendon disorders related to fluoroquinolones. Pregnancy, women of childbearing potential not using contraception, breast-feeding. Children or adolescents below 18 years of age.

Warnings and Precautions: Patients who have previously experienced serious adverse reactions using quinolone/fluoroquinolones: avoid use. Treatment of these patients should only be initiated in the absence of alternatives and after careful risk/benefit assessment. Contraception: effective contraception must be used during treatment of sexually mature women. Aortic aneurysm and dissection, and heart valve regurgitation/incompetence: epidemiology studies report an increased risk of aortic aneurysm and dissection, particularly in elderly patients, and of aortic and mitral valve regurgitation after intake of fluoroquinolones. Cases of aortic aneurysm and dissection, sometimes complicated by rupture (including fatal ones), and of regurgitation/incompetence of any of the heart valves have been reported in patients receiving fluoroquinolones. 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