Prescribing Information for Northern Ireland can be found on Page 2

Prescribing Information (Great Britain)
TENKASI (oritavancin)
Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.
Presentation: Tenkasi 400 mg powder for concentrate for solution for infusion. Each vial contains oritavancin diphosphate equivalent to 400 mg oritavancin. **Indication**: Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults and paediatric patients aged 3 months and older. Consideration should be given to official guidance on appropriate use of antibacterial agents. **Dosage and administration**: Adults: 1200 mg administered as a single dose by intravenous (IV) infusion over 3 hours. Patients aged ≥3 months to <18 years: 15 mg/kg as a single dose by IV infusion over 3 hours (maximum 1200 mg). Elderly: No dosage adjustment required for patients ≥ 65 years. Renal impairment: No dosage adjustment required for mild or moderate renal impairment. (Pharmacokinetics of oritavancin in severe renal impairment has not been evaluated). Oritavancin is not removed from blood by haemodialysis procedures. Hepatic impairment: No dosage adjustment for hepatic impairment but caution in patients with severe hepatic impariment (Child-Pugh Class C). Paediatric population: Safety and efficacy in patients < 3 months of age have not yet been established. **Contraindications**: Hypersensitivity to active substance or to any excipient. Use of IV heparin sodium is contraindicated for 120 hours after oritavancin administration because activated partial thromboplastin time (aPTT) test results may remain falsely elevated for up to 120 hours after oritavancin administration. **Warnings and Precautions**: Hypersensitivity reactions Serious hypersensitivity reactions, including anaphylactic reactions and anaphylactic shock have been reported. Cross-hypersensitivity: there should be careful monitoring of patients with any history of glycopeptide hypersensitivity during and after infusion. Infusion related reactions Oritavancin can cause reactions such as flushing of the upper body, urticaria, pruritis and/or rash. Infusion-associated reactions characterized by chest pain, chest discomfort, chills, tremor, back pain, neck pain, dyspnoea, hypoxia, abdominal pain and fever have been observed. Need for additional antibacterial agents Oritavancin is active against Gram-positive bacteria only. In mixed infections where Gram negative and/or certain types of anaerobic bacteria are suspected, oritavancin should be co-administered with appropriate antibacterial agent(s). Concomitant use of warfarin Oritavancin artificially prolongs prothrombin time (PT) and international normalised ratio (INR) for up to 12 hours, making the monitoring of the anticoagulation effect of warfarin unreliable up to 12 hours after an oritavancin dose. Interference with assay for coagulation tests Oritavancin concentrations that are found in the blood of patients following administration of a single dose have been shown to artificially prolong: aPTT for up to 120 hours, PT and INR for up to 12 hours, *Activated Clotting Time* for up to 24 hours, *Silica Clot Time* for up to 18 hours, and *Dilute Russell's Viper Venom Test* for up to 72 hours. *Clostridioides difficile*-associated diarrhoea Antibacterial-associated colitis and pseudomembranous colitis have been reported for oritavancin and may range in severity from mild to life-threatening diarrhoea. Superinfection Antibacterial products may increase the risk of overgrowth of non-susceptible micro-organisms. Osteomyelitis In phase 3 trials, more cases of osteomyelitis were reported in the oritavancin-treated arm than in the vancomycin-treated arm. Monitor patients for signs and symptoms of osteomyelitis after administration of oritavancin. Abscess In phase 3 trials, slightly more newly emergent abscesses were reported in the oritavancin-treated arm than in the vancomycin-treated arm (4.6% vs 3.4%). Limitations of the clinical data In the two major trials in ABSSSI, infections treated were confined to cellulitis, abscesses and wound infections. Interactions: Oritavancin is a weak *inhibitor* (CYP2C9 and CYP2C19) and weak *inducer* (CYP3A4 and CYP2D6) of several CYP isoforms. Caution when administering oritavancin concomitantly with products that have a narrow therapeutic window and are predominantly metabolised by affected CYP450 enzymes (e.g. warfarin), as co-administration may alter concentrations of the narrow therapeutic range product. Incompatibilities: Sodium chloride solution should not be used for dilution as it may cause precipitation. Therefore, other substances, additives or other medicinal products mixed in sodium chloride solution for IV use should not be added to oritavancin single-use vials or infused simultaneously through the same IV line or through a common IV port. In addition, medicinal products formulated at a basic or neutral pH may be incompatible with oritavancin. Reconstitution: Oritavancin powder must be *reconstituted* with water for injections and the resulting concentrate must be *diluted* in glucose 5% IV infusion prior to use. For single use only. Prepare oritavancin using aseptic technique in a pharmacy. Pregnancy and lactation: Avoid oritavancin during pregnancy unless potential benefit justifies potential risk to the foetus. Breast-feeding: a risk to the newborns/infants cannot be excluded. Driving and use of machinary: Dizziness may occur which can affect driving and use of machines. **Adverse reactions**: The most commonly reported adverse reactions were nausea, hypersensitivity and infusion site reactions, and headache. The most commonly reported serious adverse reaction was cellulitis (1.1%). The most common reported reasons for discontinuation were cellulitis (0.4%) and osteomyelitis (0.3%). Common adverse reactions as reported in pooled phase 3 ABSSSI trials (and not listed above) included abscess, anaemia, dizziness, tachycardia, vomiting, diarrhoea, constipation, abnormal liver function tests, urticaria, rash, pruritis, myalgia, infusion site reactions (including phlebitis, erythema, extravasation, induration, peripheral oedema). Uncommon and rare: hypoglycaemia, increased blood bilirubin, hyperuricaemia, eosinophilia, thrombocytopenia, hypersensitivity, anaphylactic reaction, anaphylactic shock [unknown frequency], tremor*, bronchospasm, wheezing, dyspnoea*, hypoxia*, back/neck/chest/abdominal pain*, chest discomfort*, pyrexia*, chills*, leucocytoclastic vasculitis, angioedema, erythema multiforme, flushing, tenosynovitis. [* may be infusion-related]. From one trial of 38 paediatric patients (and observed in no more than 1 patient): irritability, electrocardiogram QT prolonged (transient, asymptomatic), *Clostridioides difficile* colitis. In the event of overdose, supportive measures should be taken. Refer to SmPC for detail.
Package quantities and price: £1500 per pack (containing 3 vials of oritavancin 400 mg).
Legal category: POM.
Marketing Authorisation Holder: Menarini International Operations Luxembourg S.A.
Marketing Authorisation number: PLGB 16239/0060.
Marketed by: A. Menarini Farmaceutica Internazionale SRL. Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH. Further information is available on request to A. Menarini Farmaceutica Internazionale SRL.
Prescribing Information last updated: 24 January 2024.

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: 0800 085 8678 or email: menarini@medinformation.co.uk

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