



**Final Appraisal Recommendation**  
Advice No: 3016 – November 2016

**Levofloxacin (Quinsair®) 240 mg nebuliser solution**

**Chiesi Limited**

**Recommendation of AWMSG**

**Levofloxacin (Quinsair®) is recommended as an option for restricted use within NHS Wales.**

**Levofloxacin (Quinsair®) should be restricted for use as a third-line therapy in patients who do not respond to, or are intolerant of, second-line treatment with tobramycin for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis.**

**Levofloxacin (Quinsair®) is not recommended for use within NHS Wales outside of this subpopulation.**

**This recommendation applies only in circumstances where the approved Wales Patient Access Scheme (WPAS) is utilised or where the list/contract price is equivalent or lower than the WPAS price.**

**Additional note(s):**

- AWMSG considered that levofloxacin (Quinsair®) satisfied the AWMSG criteria for appraising orphan and ultra-orphan medicines and medicines developed specifically for rare diseases.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1012), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.

Marketing authorisation holder on first issue	Horizon Pharma plc
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