Zorginstituut Nederland

Levofloxacin (Quinsair®)

Summary of recommendations by Zorginstituut Nederland dated 3 May 2016

Zorginstituut Nederland carried out a marginal assessment of the medicine levofloxacin (Quinsair®), whereby they came to the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), levofloxacin can be regarded as mutually replaceable with three other drugs for the treatment of chronic pulmonary infections due to *Pseudomonas aeruginosa*, so it can be included in the GVS on List 1A in cluster 0J01GBAII V with a standard dose of 240 mg.

Background

In a letter dated 11 April 2016 (CIBG-16-02033), the Minister of Health, Public Welfare and Sport asked Zorginstituut Nederland to carry out a marginal assessment of whether levofloxacin (Quinsair®) could be included in the GVS system. Zorginstituut Nederland has now completed this assessment.

The manufacturer asked for levofloxacin to be placed in cluster 0J01GBAII V with three other drugs. This complies with the criterion for marginal assessment that at least three drugs are included in the cluster.

Levofloxacin is available as nebuliser solution. The solution contains levofloxacin hemihydrate equivalent to 100 mg of levofloxacin.

It is registered for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult patients with cystic fibrosis. The recommended dose is 240 mg (= 1 ampoule), administered by inhalation twice daily, with a meticulous 12-hour interval. Levofloxacin is taken in alternating cycles of 28 days followed by 28 days off treatment. Cyclic therapy may be continued for as long as the physician considers that the patient is obtaining clinical benefit.

Outcome of the assessment

Based on current mutual replaceability criteria, levofloxacin nebuliser can be regarded as mutually replaceable with the three other drugs administered via inhalation to patients with cystic fibrosis for the treatment of chronic pulmonary infections due to *Pseudomonas aeruginosa*. These drugs, tobramycin (Tobi®, Bramitob®), aztreonam (Cayston®) and colistin (Colistin®, Colobreathe® and Tadim®), are already included in the GVS, in cluster 0J01GBAII V.

Zorginstituut Nederland's advice

Zorginstituut Nederland advises the Minister of Public Health, Welfare and Sport to include levofloxacin inhalation fluid in the GVS on list 1A, in cluster 0J01GBAII V, with a standard dose of 240 mg.

For further information, please contact: JBoer@zinl.nl; warcg@zinl.nl

The original text of this advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.