

Levofloxacin 750mg tablet

Product:

LEVOFLOXACIN (Levaquin®) 750mg tablet (additional dosage strength)

Class of drugs:

Antibacterial agent; Fluoroquinolones

Indication:

Treatment of specific bacterial infections

Manufacturer:

Janssen-Ortho Inc.

CED Recommendation

The CED recommended that levofloxacin (Levaquin) 750mg tablet not be funded through the Ontario Public Drug Programs, on the basis that this product does not provide added therapeutic value over existing funded alternatives.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund levofloxacin (Levaquin) 750mg tablet.

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Levofloxacin (Levaquin) is an antibiotic used in the treatment of respiratory tract, skin and urinary tract infections. Levofloxacin (Levaquin) 250mg and 500mg tablets are currently listed on the Ontario Drug Benefit Formulary. The 750mg tablet is an additional dosage strength developed by the manufacturer to facilitate the administration of a high-dose, short-course regimen in the treatment of community-acquired pneumonia (chest infection) and acute bacterial sinusitis (sinus infection).
- ◆ Clinical studies in patients with community-acquired pneumonia and acute bacterial sinusitis indicate that levofloxacin (Levaquin) 750mg tablets taken once daily for five days provides comparable efficacy and safety as levofloxacin (Levaquin) 500mg tablets taken once daily for 10 days.
- ◆ There is no clinical trial evidence that this high-dose, short-course levofloxacin (Levaquin) regimen improves patient adherence, decreases the side effects of treatment, or reduces the risk of antibiotic resistance (loss of effectiveness of the antibiotic).
- ◆ The Committee noted the potential for inappropriate use of levofloxacin (Levaquin) for the treatment of non-bacterial sinusitis. The majority of sinusitis (>80%) is caused by viruses rather than bacteria and, therefore, is not impacted by antibiotic therapy.
- ◆ Levofloxacin (Levaquin) 750mg tablet costs \$9.45 per tablet. It is slightly less expensive than the combined costs of the 250mg and 500mg tablets. However, the Committee noted that generic levofloxacin will be available in the near future at a substantially lower cost. Moreover, any expanded or inappropriate use of this drug could easily undo the small price advantage.

- ◆ Overall, the Committee indicated that **levofloxacin (Levaquin) 250mg and 500mg tablets are already available on the Formulary. There is no evidence that the 750mg tablet provides added clinical benefit. Moreover, this drug is unlikely to provide cost-savings to the Ministry given the eventual availability of generic levofloxacin and there is an added risk of inappropriate use.**

Background:

Levofloxacin (Levaquin) belongs to a class of antibiotics called fluoroquinolones, or simply quinolones. Quinolones are used to treat a variety of infections, principally urinary tract, skin, and respiratory tract infections.

Levofloxacin (Levaquin) 250mg and 500mg tablets are listed on the Ontario Drug Benefit Formulary as Limited Use benefits. The 750mg tablet is an additional dosage strength marketed to be used as a shortened course of treatment in community-acquired pneumonia and acute bacterial sinusitis.

Detailed Discussion:

- ◆ No additional details. The full CED discussion is as outlined in the *Highlights of Recommendation* section.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review levofloxacin (Levaquin) 750mg tablet.