AVELOX® (MOXIFLOXACIN HCl)

Description

Avelox® (moxifloxacin hydrochloride) is an antibiotic in the fluoroquinolone class. Avelox is currently approved in 104 countries for the oral formulation and 76 countries for the I.V. formulation. To date, there have been more than 42 million patient uses of Avelox (and approx. 853,000 treated with I.V. moxifloxacin) worldwide.

Avelox was approved in Germany in September 1999 and by the U.S. Food and Drug Administration (FDA) in December 1999 for the treatment of respiratory tract infections (RTIs). The I.V. formulation was approved in November 2001.

Indications and Usages

The recommended therapeutic dose of Avelox oral is 400 mg taken once daily for the following treatment durations:

- 5-10 days for acute exacerbations of chronic bronchitis (AECB)
- 10 days for community acquired pneumonia (CAP), except severe cases
- 7 days for acute bacterial sinusitis (ABS), adequately diagnosed

Efficacy

Avelox has been extensively studied in the treatment of respiratory tract infections, including ABS, AECB and CAP, with an overall average response rate of 92% in 24 clinical studies that enrolled over 20,000 patients.1

Key clinical papers:

AECB

A multi-center, multi-national, randomized, double blind study (MOSAiCII) was conducted on 1,935 chronic bronchitis patients who had a history of smoking and AECB. Baseline health status was assessed prior to enrollment in the study. Upon first exacerbation, patients were randomized to either Avelox 400 mg daily for 5 days or 7 days of comparator therapy (either amoxicillin 500 mg tds, clarithromycin 500 mg bd or cefuroxime-axetil 250 mg bd). Patients were then followed up for 9 months or until their next exacerbation.

- Patients who received Avelox for five days experienced a significantly improved clinical cure rate (70.9% vs. 62.8%) as well as significantly higher bacteriological eradication rates (91.5% vs. 81%) over those who received a seven-day course of standard antibiotic therapy. Clinical cure was defined as return to baseline health status.
- Patients who received Avelox experienced a significantly longer exacerbation-free interval (132.8 days vs. 118 days) than comparator. Additionally, significantly fewer patients who took Avelox required additional post-therapy antibiotics to achieve clinical resolution of AECB (7.6% of Avelox patients vs. 14.1% of patients taking standard therapy in the “intent-
to-treat” population and 8.8% Avelox vs. 14.8% standard therapy in the per-protocol population).

**CAP**

A prospective, randomized, multinational, double-blind study (CAP 2000\(^{III}\)) was conducted on 564 patients with CAP, comparing Avelox 400 mg daily for 10 days to standard therapy of either amoxicillin (1 g tid) alone or given in combination with clarithromycin (500 mg bid) for up to 14 days. The results showed:

- Oral Avelox monotherapy was as effective as standard combination therapy (93.5% vs. 93.9%, \(p=ns\))
- In terms of drug related adverse events, Avelox was significantly better tolerated than comparator regimen

**ABS**

A prospective, randomized multi-centre study\(^{IV}\) was conducted on 242 patients with acute bacterial sinusitis. Patients were randomized to either Avelox 400 mg daily for 7 days or cefuroxime axetil 250 mg bd for 10 days. The results showed:

- Clinical success rate of Avelox was significantly higher in the Avelox group than the comparator (96.7% vs. 90.7%)

**Safety**

Avelox is a prescription medication that is generally well-tolerated. The most common side effects, which are usually mild, include nausea, diarrhea, and dizziness.

For Avelox prescribing information and indicated organisms, log on to [www.avelox.com](http://www.avelox.com) or email global.avelox@bayer.com.

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