

AIR...Avelox®:

# Success is... reliable.

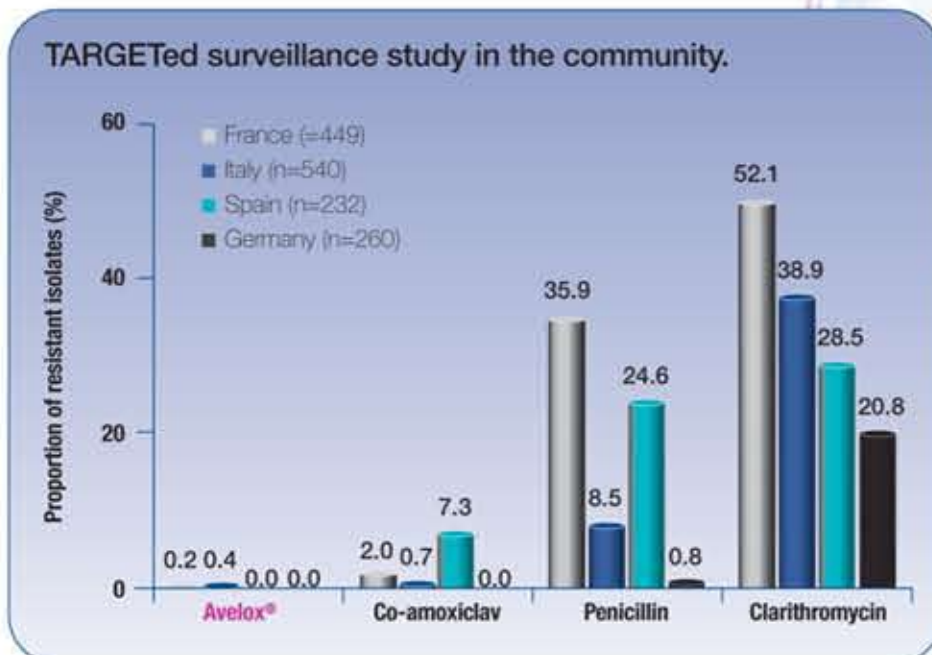
Avelox®: Targeted coverage of the key causative respiratory pathogens.

	Pathogen	Amoxicillin <sup>6</sup>	Co-amoxiclav <sup>7</sup>	Doxycycline <sup>8</sup>	Clarithromycin <sup>9</sup>	Avelox <sup>10</sup>
Gram-positive	<i>Streptococcus pneumoniae</i>	■	■	■	■	■
Gram-negative	<i>Haemophilus influenzae</i>	■	■	■	■	■
	<i>Moraxella catarrhalis</i>	■	■	■	■	■
Atypical	<i>Chlamydia pneumoniae</i>	■	■	■	■	■
	<i>Mycoplasma pneumoniae</i>	■	■	■	■	■
	<i>Legionella</i> spp.	■	■	■	■	■

German SPC data, local information regarding resistance situation required. In Europe, acquired resistance to amoxicillin/co-amoxiclav in *S. pneumoniae* up to 26%. Incidence of beta-lactamase producing *H. influenzae* naturally resistant to amoxicillin varies across countries.

■ Commonly susceptible species      ■ Inherently resistant organisms  
■ Species for which acquired resistance may be a problem      ■ SPC does not specify

Avelox®: Very low rates of *S. pneumoniae* resistance.<sup>11</sup>



AIR...Avelox®:

# Success is... powerful.

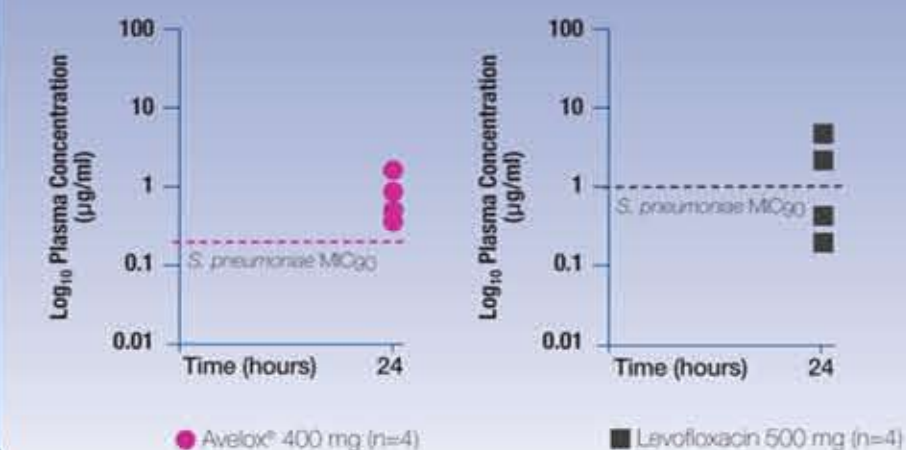
Avelox®: The fluoroquinolone with higher anti-pneumococcal activity than levofloxacin.<sup>12</sup>

MIC<sub>90</sub> against *S. pneumoniae* (µg/ml).<sup>11</sup>

Avelox®	0.25
Levofloxacin	1.0

Avelox®: High and sustained plasma concentrations.<sup>13</sup>

Individual steady-state plasma concentrations at 24h after the administration of the last dose.



- Avelox® concentrations exceeded the MIC<sub>90</sub> of *S. pneumoniae*, while 2 out of 4 patients failed to maintain levofloxacin concentrations above the MIC<sub>90</sub> at 24h
- Avelox® also exceeded levofloxacin concentrations at 24h in epithelial lining fluid and alveolar macrophages

6. Avelox-Sandoz 250/1000 mg German Summary of Product Characteristics April 2008.  
7. Amoxiclav-Sandoz 875/125 mg German Summary of Product Characteristics September 2008.  
8. Doxycycline STADA 100/200 German Summary of Product Characteristics July 2008.  
9. Clarithromycin STADA 250/500 German Summary of Product Characteristics November 2008.  
10. Avelox oral Summary of Product Characteristics, October 2008.  
11. Morrissey I et al. Int J Antimicrob Agents. 2007; 30:345-351.  
12. Woodhead M et al. Eur Respir J 2005; 26: 1126-1130.  
13. Capitano B et al. Chest 2004; 125:965-973.



## Avelox®: A valuable option for the treatment of AECB, ABS and CAP in appropriate patients at risk of a poor outcome.\*

- Fast bacterial eradication of the key respiratory pathogens<sup>28</sup>
- Rapid and long-lasting symptom resolution in AECB<sup>14,15</sup>
- High clinical success rates in AECB, ABS and CAP<sup>14,18,21</sup>
- Good tolerability and extensive clinical experience with over 117 million patients treated worldwide<sup>29</sup>
- Extensively investigated in over 14,000 patients in clinical trials and in 92,000 patients in post-marketing surveillance studies<sup>29</sup>
- Easy to use
  - 1 x 400 mg tablet once daily for 5 to 10 days facilitates patient compliance
  - No dose adjustments required for the elderly, patients with low body weight or patients with renal impairment



28: Odenkoff J. *Clin Infect Dis* 2001; **58**: 900-905  
 14: Wilson R et al. *Chest* 2004; **125**: 953-964  
 15: Mizutani M et al. *Clin Drug Invest* 2004; **24**: 263-72  
 18: Porter H et al. *Eur J Clin Microbiol Infect Dis* 2005; **25**: 367-376  
 21: Siegel R et al. *Respir Med* 2000; **94**: 337-344  
 29: <http://www.avelox.com> (accessed July 20, 2009).

\* Avelox should be used in accordance with the full Summary of Product Characteristics.

**AVELOX® 400mg FILM-COATED TABLETS, AVELOX® 400mg/250ml SOLUTION FOR INFUSION (MOXIFLOXACIN):** Refer to local prescribing information for full details before prescribing. **Tablets** each contain 400mg moxifloxacin as hydrochloride. **Solution for infusion** contains moxifloxacin 1.6mg/ml (400mg/250ml), as moxifloxacin hydrochloride. **Indications:** Bacterial infections caused by moxifloxacin susceptible bacteria as follows: **Tablets: adequately diagnosed** acute exacerbation of chronic bronchitis and acute bacterial sinusitis only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections or when these have failed to resolve the infection; community acquired pneumonia, except severe cases only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of this infection; mild to moderate pelvic inflammatory disease without an associated tubo-ovarian or pelvic abscess in combination with another appropriate agent unless moxifloxacin resistant *Neisseria gonorrhoeae* can be excluded. **Solution for infusion:** community acquired pneumonia and complicated skin and skin structure infections in patients requiring initial parenteral therapy only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of these infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Refer to SmPC and/or local laboratory guidelines for microbiological activity. **Dosage/Use: Adults: Tablets** 400mg once daily for 5-10 days in acute exacerbation of chronic bronchitis, 7 days in acute sinusitis, 10 days in community acquired pneumonia and 14 days in mild to moderate pelvic inflammatory disease. **Solution for infusion intravenous dose** of 400mg once daily (can be administered via a T-tube, with compatible infusion solutions), the duration of infusion should not be less than the recommended 60 minutes and the intravenous dose of 400 mg once a day should not be exceeded (QT prolongation may increase with increasing plasma concentrations due to rapid i.v. infusion). Initial i.v. use may be followed by oral administration. For sequential administration total treatment duration depends on indication, type and severity of disease and clinical response; community acquired pneumonia, 7-14 days; complicated skin and skin structure infections, 7-21 days. No dose adjustment in elderly or patients with low body weight, in impaired renal function or in patients on chronic dialysis. Insufficient data in patients with severely impaired liver function. Efficacy and safety not established in children and adolescents. **Contraindications:** Hypersensitivity to moxifloxacin, other quinolones or excipients; pregnancy, lactation, patients below 18 years of age; history of quinolone related tendon disease/disorder; congenital or documented acquired QT prolongation; electrolyte disturbances; clinically relevant bradycardia or heart failure; previous history of symptomatic arrhythmias; concurrent use with drugs that prolong QT interval; impaired liver function (Child Pugh C); transaminase increase > 5 fold ULN. **Warnings/Precautions:** Prolongation of the QT interval: use with caution in patients on concomitant medication that can reduce potassium levels/induce clinically significant bradycardia or with ongoing proarrhythmic conditions (if signs of cardiac arrhythmia develop, stop treatment and perform ECG); use with caution in female and elderly patients who may be more sensitive to the effects of QTc-prolonging drugs; use with caution in patients with CNS disorders which may predispose to seizures or lower the seizure threshold; consult an eye specialist immediately if vision becomes impaired/any effects on the eyes are experienced; risk of tendon inflammation and rupture, particularly in the elderly and those on concurrent treatment with corticosteroids (discontinue and rest affected limb); fulminant hepatitis (potentially leading to life-threatening liver failure) – contact doctor before continuing treatment if signs/symptoms develop i.e. rapidly developing asthenia with jaundice, dark urine, bleeding tendency or hepatic encephalopathy; perform liver function tests where indications of liver dysfunction occur; use with caution in patients with a family history of or actual defects in glucose-6 phosphate dehydrogenase activity (risk of haemolytic reaction); risk of antibiotic associated colitis (incl. pseudomembranous colitis); avoid exposure to UV irradiation or extensive and/or strong sunlight; hypersensitivity/allergic/anaphylactic reactions (discontinue and treat); caution in elderly patients with renal disorders if unable to maintain adequate liquid intake. May impair ability to drive or operate machinery due to CNS reactions. Moxifloxacin is not recommended for the treatment of MRSA infections. In case of a suspected or confirmed infection due to MRSA, treatment with an appropriate antibacterial agent should be started. **For Solution for infusion only:** Avoid intra-arterial administration. Initiate cautiously and monitor carefully. Incompatible with sodium chloride 10% and 20% solutions, sodium bicarbonate 4.2% and 8.4% solutions. Efficacy in severe burn infections, tussitis, major abscesses and diabetic foot infections with osteomyelitis not established. Experience of sequential intravenous/oral moxifloxacin in severe community-acquired pneumonia is limited. Contains 787mg (approximately 34mmol) sodium per dose; take into consideration for patients on a controlled sodium diet. **For Tablets only:** Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose maldigestion should not take this medicine. Consider risk-benefit ratio in less severe infections. **Interactions:** Additive effect between moxifloxacin and QT prolonging drugs (antiarrhythmics class IA and III, neuroleptics, tricyclic antidepressants, certain antimicrobials, certain antihistamines, cisapride, vincamine IV, bepridil, diphemanil), cannot be excluded. Interactions with digoxin (no precaution required) and gliclazide (not clinically relevant). May affect anticoagulant activity – care required with concomitant use of warfarin or other anticoagulants. **Tablets:** Leave 6 hours before administering bivalent or trivalent cations (e.g. antacids containing magnesium, aluminium, sucrafate, zinc or iron salts or didanosine). Avoid charcoal (except in overdose). **Undesirable effects:** Most common: nausea, diarrhoea, gastrointestinal/abdominal pain, vomiting, headache, dizziness, QT prolongation in patients with hypokalaemia, increase in transaminases, superinfections due to resistant organisms and, in i.v. treated patients, injection site reactions and increased gamma GT. Less common: disorders of the blood and lymphatic system, allergic reactions including rare cases of anaphylactic shock and allergic oedema/angioedema (potentially life threatening laryngeal oedema), metabolic and nutritional disorders, nervous system and psychiatric disorders, including depression (in very rare cases, culminating in self-endangering behaviour), disorders of the eye, ear, cardiovascular (including ventricular tachyarrhythmias, and very rare cases of Torsades de Pointes and cardiac arrest), respiratory, gastrointestinal disorders including rare cases of pseudomembranous colitis (in very rare cases, associated with life-threatening complications), fulminant hepatitis, potentially leading to life-threatening liver failure (including fatal cases), skin and subcutaneous tissue disorders (including very rare cases of bullous skin reactions like Stevens-Johnson syndrome or toxic epidermal necrolysis, potentially life-threatening); musculoskeletal and connective tissue (including, in very rare cases, exacerbation of symptoms of myasthenia gravis), renal and urinary system disorders, feeling unwell, painful conditions, sweating and oedema. I.V. treated patients (with or without initial oral therapy) have a higher incidence of increased gamma GT, ventricular tachyarrhythmias, hypotension, oedema, antibiotic associated colitis incl. pseudomembranous colitis (in very rare cases associated with life threatening complications), seizures including grand mal convulsions, hallucinations, renal impairment/failure. Transient loss of vision, hypernatraemia, hypercalcaemia, haemolysis and photosensitivity have been reported in patients treated with other fluoroquinolones. Since dosage forms, indications or other information may vary from country to country, please consult your local prescribing information. For further information contact the local Bayer Schering Pharma subsidiary or Bayer Schering Pharma AG, BU GM PC GBT Avelox®, 13342 Berlin. **Date of preparation:** July 2009. © Registered trademark of Bayer AG, Germany



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