Safety and tolerability of moxifloxacin in the treatment of respiratory tract infections: a post-marketing surveillance conducted in Indonesia

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Abstrak

Tablet moxifloxacin 400 mg telah dipasarkan di Indonesia untuk beberapa indikasi, yaitu bronkitis kronik eksaserbasi akut, pneumonia didapat di komunitas, dan sinusitis bakterial akut. Untuk menilai keamanan dan tolerabilitas moxifloxacin, dilakukan survei pasca pemasaran pada tahun 2001 yang melibatkan 589 dokter. Selain itu, dinilai pula efikasi kliniknya, baik oleh dokter maupun pasien, dengan menggunakan total skor 6 gejala yang berskala 0-12. Seluruhnya, diperoleh 1715 pasien dengan sinusitis akut, pneumonia didapat di komunitas, bronkitis kronik eksaserbasi akut dan infeksi lainnya yang diobati dengan moxifloxacin oral 400 mg sekali sehari. Sebanyak 151 (8,8%) pasien melaporkan efek samping dan 5 (0.29%) pasien mengalami efek samping serius, yang dianggap berhubungan dengan terapi moxifloxacin. Efek samping tersering adalah mual (4.96%), pusing (1.52%), muntah (0.64%), sakit kepala (0,47%), dan lemah (0,47%). Duapuluh tiga (1,34%) pasien menghentikan terapi akibat efek samping. Toleransi terhadap terapi dinilai sangat baik oleh 647 (37,7%) dan baik oleh 919 (53,6%) pasien. Berdasarkan penilaian klinis oleh dokter, 57,7% pasien dinyatakan sembuh dan 39.9% dinyatakan membaik di akhir terapi. Rerata skor gejala total, sebagaimana dinilai oleh pasien, turun dari 6,43 pada hari pertama menjadi 2,76 pada hari ketiga. Secara umum, 95.3% pasien merasa lebih baik setelah mendapat moxifloxacin dan 97,6% pasien memberikan kesan baik terhadap terapi moxifloxacin. Sebagai kesimpulan, survei pasca pemasaran ini menunjukkan bahwa pengobatan infeksi saluran napas oleh bakteri, terutama bronkitis, pneumonia komunitas dan sinusitis, dengan moxifloxacin 400 mg sekali sehari aman dan dapat ditoleransi dengan baik, dan juga bahwa moxifloxacin sangat efektif untuk pengobatan infeksi ini dengan perbaikan gejala yang cepat. (Med J Indones 2004; 14: 11-19)

<hr><i>Moxifloxacin 400 mg tablet has been marketed in Indonesia for several indications, i.e. acute exacerbation of chronic bronchitis (AECB), community-acquired pneumonia (CAP), and acute bacterial sinusitis (ABS). To assess the safety and tolerability of moxifloxacin, a post-marketing surveillance study was conducted in the year 2001 involving 589 physicians. Clinical efficacy was also evaluated, both by physicians and patients, using a 6-symptom total score, which was scaled 0-12. A total of 1715 patients with acute sinusitis, CAP, AECB, and other infections were treated with oral moxifloxacin 400 mg once daily. There were 151 (8.8%) patients with adverse events (AEs) and 5 (0.29%) patients with serious adverse events (SAEs) that were considered related to moxifloxacin treatment. The most common adverse reactions were nausea (4.96%), dizziness (1.52 %), vomiting (0.64%), headache (0.47%), and weakness (0.47%). Twenty three (1.34%) patients discontinued treatment due to adverse events. Tolerance to treatment was rated very good and good by 647 (37.7%) and 919 (53.6%) of patients, respectively. Based on physicians? clinical assessment, 57.7% of patients were cured and 39.9% were improved at the end of treatment. Mean total symptom score, as assessed by the patients, decreased from 6.43 on day-1 to 2.76 on day-3. Totally, 95.3% of patients felt better after receiving moxifloxacin and 97.6% of patients had good impression on moxifloxacin treatment. In conclusion, treatment of respiratory tract infections, mainly AECB, CAP and

ABS, with moxifloxacin 400 mg once daily in this post-marketing surveillance was shown to be safe and well tolerated. Moxifloxacin was also shown to be highly effective in the treatment of these infections with rapid improvement of symptoms. (Med J Indones 2004; 14: 11-19)</i>