

Sanofi-Synthelado
SL77.0499-10 (ALFUZOSIN)
Bibliography

1. Malik M. Problems of heart rate correction in assessment of drug-induced QT interval prolongation. *J Cardiovasc Electrophysiol* 2001; 12:411-20.
2. Hnatkova K, Malik M. "Optimum" formulae for heart rate correction of the QT interval. *PACE* 1999; 22:1683-7.
3. Badilini F, Maison-Blanche P, Childers R, Coumel P. QT interval analysis on ambulatory ECG recordings: a selective beat averaging approach. *Med Biol Eng Comput* 1998; 36:1-10.
4. Extramiana F, Maison-Blanche P, Badilini F, Pinoteau J, Deseo T, Coumel P. Circadian modulation of QT rate dependence in healthy volunteers: gender and age differences. *J Electrocardiol* 1999; 32:33-43.
5. Preliminary concept paper: The clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs. Revised version 6 February 2003.
6. USFDA: summary basis of approval to NDA 21-085, sup 10 for moxifloxacin - Approved 27 April 2001. (Not provided).
7. Rhodes PR, Krogh RH, Bruskewitz RC. Impact of drug therapy on benign prostatic hyperplasia-specific quality of life. *Urology* 1999; 53:1090-8.
8. Jardin A, Bensadoun H, Delauche-Cavallier MC, et al. Alfuzosin for treatment of benign prostatic hypertrophy. *Lancet* 1991; 337:1457-61.
9. Teillac P, Delauche-Cavallier MC, Attali P, et al. Urinary flow rates in patients with benign prostatic hypertrophy following treatment with alfuzosin, *Br J Urol* 1992; 70:58-64.
10. Jardin A, Bensadoun H, Delauche-Cavallier MC, et al. Long-term treatment of benign prostatic hyperplasia with alfuzosin: a 12-18 month assessment. *Br J Urol* 1993; 72:615-20.
11. Jardin A, Bensadoun H, Delauche-Cavallier MC, et al. Long-term treatment of benign prostatic hyperplasia with alfuzosin: a 24-30 month survey. *Br J Urol* 1993; 74:579-84.

12. Buzelin JM, Roth S, Geffriau-Ricouard C, Delauche-Cavallier MC, et al. Efficacy and safety of sustained release alfuzosin 5 mg in patients with benign prostatic hyperplasia. Eur Urol 1997; 31:190-8.
13. Debruyne FMJ, Jardin A, Colloï D, et al. Sustained-release alfuzosin, finasteride and the combination of both in the treatment of benign prostatic hyperplasia. Eur Urol 1998; 34:169-75.
14. McNeill SA, Daruwala PD, Mitchell IDC, et al. Sustained-release alfuzosin and trial without catheter after acute urinary retention: a prospective, placebo-controlled trial. BJU Int 1999; 84:622-7.
15. *Physicians's Desk Reference 2003*, Hytrin Monographs.
16. *Physicians's Desk Reference 2003*, Cardura.
17. *Physicians's Desk Reference 2003*, Flomax.
18. Funck-Brentano C, Jaillon P. Rate-corrected QT interval: Techniques and limitations. Am J Cardiol 1993;72:17B-22B.
19. Haverkamp W, Breithardt G, Camm AJ, Janse MJ, Rosen MR, Antzelevitch C, et al. The potential for QT prolongation and proarrhythmia by non-antiarrhythmic drugs: Clinical and regulatory implications. Report on a policy conference of the European Society of Cardiology. Eur Heart J 2000; 21:1216-31.
20. Malik M, Camm AJ. Evaluation of drug-induced QT interval prolongation. Implications for drug approval and labelling. Drug Safety 2001; 24(5):323-51.
21. Malik M. The imprecision heart rate correction may lead to artificial observations of drug induced QT interval changes. PACE 2002; 25(2):209-16.
22. Aytemir K, Maarouf N, Gallagher MM, Yap YG, Waktare JEP, Malik M.
 - a. Comparison of formulae for heart rate correction of QT interval in exercise electrocardiograms. PACE 1999; 22:1397-1401.
23. Bonate PL, Russell T. Assessment of QTc prolongation for non-cardiac-related drugs from a drug development perspective. J Clin Pharmacol 1999; 39:349-58.
24. NDA 20-919: Zeldox (ziprasidone mesylate IM, Pfizer.) Briefing information. Pfizer. 15 Feb 2001 <http://www.fda.gov/ohrms/dockets/ac/01/briefing/3685b2.htm>. (Not provided).
25. Ketek (telithromycine) Briefing Information, Aventis. 26 April 2001 <http://www.fda.gov/ohrms/dockets/ac/01/briefing/3746b1.htm>. (Not provided).

26. Malik M, Farbom P, Batchvarov V, Hnatkova K, Camm AJ. Relation between QT and RR intervals is highly individual among healthy subjects: implications for heart rate correction of the QT interval. *Heart* 2002; 87:220-8.
27. Moss AJ, Zareba W, Benhorin J, Couderc JP, Kennedy H, Locati-Heilbron E, Maison-Blanche P. ISHNE guidelines for electrocardiographic evaluation of drug-related QT prolongation and other alterations in ventricular repolarization: task force summary. A report of the Task Force of the International Society for Holter and Noninvasive Electrocardiology (ISHNE), Committee on Ventricular Repolarization. *ANE* 2001; 6(4):333-41.
28. Goodman DB.
 - a. Continuous 12-lead ECG recording. Analysis of digital ECG data. What can you do with the digitized ECG waveform that you cannot do with a paper ECG record?
 - b. Public presentation at FDA ECG data standards meeting (November 2001)
29. [http://www.fda.gov/cder/regulatory/ersr/Goodman\[1\].ppt](http://www.fda.gov/cder/regulatory/ersr/Goodman[1].ppt)
30. Molnar J, Weiss J, Zhang F, Rosenthal JE. Evaluation of five QT correction formulas using a software-assisted method of continuous QT measurement from 24-hour Holter recordings. *Am J Cardiol* 1996; 78:920-6.
31. Lepeschkin E, Surawicz B. The measurement of the Q-T interval of the electrocardiogram. *Circulation* 1952; 6:378-88.
32. Hoffman BB. Catecholamines, sympathomimetic drugs, and adrenergic receptor antagonists. In: Hardman JG, Limbird LE Gilman AG, editors. *Goodman & Gilman's The pharmacological basis of therapeutics*, 10th ed. New York: McGraw-Hill; 2001. p.215-68.
33. Stinson JC, Pears JS, Williams AJ, Campbell RWF. Use of 24 h ambulatory ECG recordings in the assessment of new chemical entities in healthy volunteers. *Br J Clin Pharmacol* 1995; 39:651-6.
34. Lukacs B, Blondin P, MacCarthy C, Du Boys B, Gripon P, Lassale C. Safety profile of 3 months' therapy with alfuzosin in 13,389 patients suffering from benign prostatic hypertrophy. *Eur Urol* 1996; 29: 29-35.
35. Shah RR. The significance of QT interval in drug development. *Br J Clin Pharmacol* 2002; 54:188-202.