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Needle-free subcutaneous sumatriptan (Sumavel DosePro): bioequivalence and ease of use.

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Abstract

BACKGROUND: Subcutaneous (s.c.) injection of sumatriptan is currently associated with needle aversion in some patients, and sharps disposal issues.

OBJECTIVES: To investigate whether a needle-free system can deliver s.c. sumatriptan. If so, to examine whether needle-free administration is bioequivalent to a 26-gauge needle-based auto-injector. Lastly, to assess the needle-free system for clinical acceptability and ease of use during migraine attacks.

METHODS: Two clinical trials. Study A: Pharmacokinetics and bioequivalence was studied in normal adult volunteers (n = 57 total), directly comparing needle-free (Sumavel DosePro) with needle-based (Imitrex STATdose System) administration of 6 mg s.c. sumatriptan. An incomplete, randomized, partial factorial, crossover design was used. Each subject received 2 administrations of each product, at 2 of the 3 anatomical sites (abdomen, thigh or arm). There were appropriate "washout" periods between each. Pharmacokinetic sampling was at standard time points, and tests for bioequivalence then followed. Study B: The term "ease of use" was used for clinical acceptability and utility of the needle-free system when it was assessed among 52 outpatients treating migraine attacks. Instructional materials were used as would be provided after ordinary prescription. The primary endpoint was successful use of the needle-free system to administer sumatriptan at the first attempt, including appropriate injection site selection. Second and subsequent uses of the needle-free system were also documented.

RESULTS: For administration sites in the thigh and the abdomen, but not the arm, the needle-free and needle-based systems were bioequivalent (for all pharmacokinetic endpoints the mean ratios between the 2 devices were always between 90.1% and 115%). Among outpatients treating a migraine attack with the needle-free system, 51 of 52 on first attempt used the needle-free system successfully when treating a migraine attack.

CONCLUSIONS: Sumavel DosePro needle-free delivery system is a new presentation of s.c. sumatriptan that delivers drug effectively, is bioequivalent to the existing needle auto-injector when used at the thigh or abdomen, and is easy to use.

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