Pharmaceutical quality of seven generic Levodopa/Benserazide products compared with original Madopar(R) / Prolopa(R)

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Author(s) Gasser, Urs E.; Fischer, Anton; Timmermans, Jan P.; Arnet, Isabelle
Author(s) at UniBasel Arnet, Isabelle ;
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BACKGROUND: By definition, a generic product is considered interchangeable with the innovator brand product. Controversy exists about interchangeability, and attention is predominantly directed to contaminants. In particular for chronic, degenerative conditions such as in Parkinson's disease (PD) generic substitution remains debated among physicians, patients and pharmacists. The objective of this study was to compare the pharmaceutical quality of seven generic levodopa/benserazide hydrochloride combination products marketed in Germany with the original product (Madopar(R) / Prolopa(R) 125, Roche, Switzerland) in order to evaluate the potential impact of Madopar(R) generics versus branded products for PD patients and clinicians. METHODS: Madopar(R) / Prolopa(R) 125 tablets and capsules were used as reference material. The generic products tested (all 100 mg/25 mg formulations) included four tablet and three capsule formulations. Colour, appearance of powder (capsules), disintegration and dissolution, mass of tablets and fill mass of capsules, content, identity and amounts of impurities were assessed along with standard physical and chemical laboratory tests developed and routinely practiced at Roche facilities. Results were compared to the original "shelf-life" specifications in use by Roche. RESULTS: Each of the seven generic products had one or two parameters outside the specifications. Deviations for the active ingredients ranged from +8.4% (benserazide) to -7.6% (levodopa) in two tablet formulations. Degradation products were measured in marked excess (+26.5%) in one capsule formulation. Disintegration time and dissolution for levodopa and benserazide hydrochloride at 30 min were within specifications for all seven generic samples analysed, however with some outliers. CONCLUSIONS: Deviations for the active ingredients may go unnoticed by a new user of the generic product, but may entail clinical consequences when switching from original to generic during long-term therapy. Degradation products may pose a safety concern. Our results should prompt caution when prescribing a generic of Madopar(R)/Prolopa(R), and also invite to further investigations in view of a more comprehensive approach, both pharmaceutical and clinical.

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