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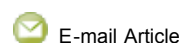
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Safety surveillance of esterified estrogens— methyltestosterone (Estratest® and Estratest® HS) replacement therapy in the United States

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Abstract

This paper summarizes all postmarketing safety surveillance data collected by Solvay Pharmaceuticals, Inc. (Marietta, Georgia), between 1989 and 1996 for Estratest® and

Estratest® HS (half-strength). These oral esterified estrogens—methyltestosterone combination products have been marketed in the United States since 1964 for the treatment of moderate-to-severe vasomotor symptoms associated with menopause in patients whose symptoms have not been relieved by estrogens alone. Between 1989 and 1996, more than 1 million woman-years of exposure occurred. The safety profile contained in this paper is based on a cumulative total of 568 individual cases comprising 863 adverse events (AEs). The proportions of AEs associated with the use of Estratest (575 events; 66.6%) and Estratest HS (288 events; 33.4%) were commensurate with the proportions of individual reports of adverse experiences for the two formulations (369 reports [65.0%] and 199 reports [35.0%], respectively). The rank order and percentage of types of AEs reported were also similar. The cumulative volume of reports was relatively low given the extent of exposure. Despite the limitations inherent in spontaneous postmarketing surveillance, the safety profile derived from this assessment does not indicate a significant safety concern with Estratest or Estratest HS. No deaths were reported, and no adverse findings indicative of the need for more comprehensive surveillance or concern on the

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part of the medical community or consumers were observed. Reports of cancer, cardiovascular disease, thromboembolic phenomena, and hepatic dysfunction were few and were assessed as not related to treatment with Estratest or Estratest HS; reports of drug overdose, drug-drug interaction, and birth defects were rare (4 of 863 events; 0.5%). The most commonly reported AEs were those known to be associated with estrogen therapy (weight gain, headache, nausea, and vasodilatation) and androgen treatment (alopecia, acne, and hirsutism). Twenty-three (4.0%) of the 568 cases reported had at least one event that was regarded as serious, and 53 (6.1%) of the total 863 AEs were regarded as serious. The findings indicate that Estratest and Estratest HS are safe when used as directed and that the marginal increase in risk associated with androgen coadministration can be managed with appropriate patient selection and monitoring, as stated in the package insert for these compounds.

Author Keywords: safety surveillance; pharma-covigilance; hormone replacement therapy; estrogen; androgen

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