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# **Safety and tolerability of testosterone patch therapy for up to 4 years in surgically menopausal women receiving oral or transdermal oestrogen.**

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## **Source**

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## **Abstract**

Two clinical trials previously demonstrated the safety of 300 µg/day transdermal testosterone patch (TTP) treatment for up to 6 months in 1094 surgically menopausal women with hypoactive sexual desire disorder (HSDD). Adverse events (AE), clinical laboratory tests, vital signs, physical examinations and mammograms were evaluated in open-label extensions of these two trials for up to 4 years and are presented in this article. Nine hundred and sixty-seven patients received at least one application of the TTP resulting in 1092 patient-years of exposure. There was no increase over time in the rate of new occurrences or severity of AEs, serious AEs, or withdrawals due to AEs. The most common AEs associated with treatment were application site reactions and unwanted hair growth; however, most were mild and rarely resulted in study withdrawal. No clinically meaningful changes in serum chemistry, haematology, lipid profile, carbohydrate metabolism, renal and liver function or coagulation parameters were noted with up to 4 years of therapy. Consistent with age-appropriate expected rates, three cases of invasive breast cancer were observed. No important changes in the safety or tolerability profile of TTP were revealed with long-term use for up to 4 years in otherwise healthy oophorectomised women with HSDD on concomitant oestrogen.

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