HIGH CONTRACEPTIVE EFFICACY AND TOLERABILITY WITH NUVARING

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NuvaRing is a novel combined contraceptive vaginal ring. Each ring is used for one cycle, comprising three weeks of continuous ring use followed by a one-week ring-free period. The contraceptive efficacy and safety of NuvaRing use for 1 year were studied in 1182 women enrolled in 52 European centers. A pregnancy test was performed before the first ring insertion and after cycle 13 and if pregnancy was suspected during the study. The investigator recorded adverse events at each study visit. Local tolerability was assessed by cervical cytology. In a second study, cytology, colposcopy and microbiology were examined.

Six pregnancies occurred in 12,109 cycles of exposure giving a Pearl Index of 0.65 (95% CI: 0.24–1.41). Three of the six women violated the NuvaRing regimen in the cycle of conception. Compliance to the prescribed regimen was high with criteria being fulfilled in 90.8% of cycles. Throughout the one-year study 41% of women did not report any adverse events. The most frequently reported treatment-related adverse events, none of which was serious, were headache (6.6%), leukorrhoea (5.3%) and vaginitis (5.0%). There was a low incidence of estrogen-associated adverse events such as nausea (2.8%) and breast tenderness (1.9%). A total of 173 women (15.1%) discontinued because of an adverse event, device-related events (comprising ring expulsion, foreign body sensation or coital problems) being the most commonly reported (2.6%). No clinically relevant changes from baseline were observed in blood biochemistry, hematology, blood pressure, heart rate or body weight. In a separate study, assessments of cervical and vaginal cytology, colposcopy and microbiology showed that NuvaRing has no unfavorable local effects on the cervix and the vagina, and is well tolerated.

NuvaRing is an effective contraceptive, as shown by a low Pearl Index in a large international study. It is well tolerated, with a good safety profile and is not associated with an increased incidence of abnormal effects on the cervix or vagina.