

Onset and prevalence of common adverse events with NuvaRing

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Objective: NuvaRing is a novel combined contraceptive vaginal ring. As NuvaRing is a low-dose method (15 µg of ethinylestradiol and 120 µg of etonogestrel daily), a low incidence of adverse events (AEs) is expected during use. A combined analysis of the onset and prevalence of general AEs monitored during clinical studies is presented.

Methods: The integrated database of all NuvaRing clinical studies was examined for both the onset (initial occurrence) and prevalence (any occurrence and/or continuation) of common AEs (defined as >5% overall incidence in the NuvaRing group) over intervals of 3 cycles.

Results: The overall incidence of the most commonly reported AEs was low: vaginitis (14.1%), headache (9.8%), upper respiratory tract (URT) infection (8.0%), leukorrhea (5.8%), sinusitis (5.7%) and nausea (5.2%). The onset of all these AEs was reported most frequently during cycles 1–3, apart from sinusitis where onset occurred most frequently during cycles 4–6. For headache, leukorrhea and nausea, the majority of cases were considered to be drug-related by the investigators (5.7%, 4.6% and 3.2%, respectively). Since the prevalence of these events decreased substantially over time, they are likely to result from the adjustment to a new contraceptive method. For vaginitis, most cases were not considered to be drug-related (8.6%), and the prevalence also decreased over time. The initial incidence and prevalence of vaginitis during cycles 1–9 indicate that most women experienced this event only once. All cases of sinusitis and URT infection were not drug-related and consequently there was no clear relationship to time for the prevalence of these events.

Conclusions: NuvaRing use is associated with a low incidence of AEs, the type of which are commonly seen during hormonal contraception use. The incidence of AEs that were considered to be related to NuvaRing use decreased over time.