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Clinical development of Ornibel ® a new generation etonogestrel/ethinylestradiol vaginal ring: Comparative tolerability, acceptance and flexibility of the new ring with Nuvaring®

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Objectives: To show the comparative tolerability, acceptability and flexibility as part of the clinical development of a recently developed contraceptive vaginal ring (Ornibel®), compared to the reference product (Nuvaring®).

Patients and Methods:

40 subjects were to complete a product questionnaire following each ring removal. Subjects were to provide their opinion using the 5-point scale with responses adapted to the following questions: 1. Do you feel comfortable using the ring? 2. Has the ring interfered with your daily activities? 3. If you had intercourse(s) during the study: Have you felt discomfort during the intercourse with the intravaginal ring? 4. If you had intercourse(s) during the study: Could the ring be felt by your partner during intercourse? 5. If the ring was accidentally expelled and you had to reinsert it during the study: Could the ring be easily reinserted?

A family physician performed a local tolerability assessment, both before insertion and after removal of each vaginal ring. Irritation, erythema, oedema and secretion, was scored after the vaginal examinations using a 4-point scale.

The flexibility of the new polymers was also tested with a dynamometer. Two tests were performed: Test A) Compressing the ring 1 cm and Test B) compressing the rings until the two sides of the ring were facing 0,5 cm.

Results

No clinically significant abnormal physical examination findings were recorded in this study. Similarity of the two products was confirmed. There were no moderate or severe signs of vaginal mucosa irritation in the subjects who received any of the assayed products.

Most subjects answered, ‘strongly agree’ when asked if they felt comfortable using the ring, without no differences observed between products (p=0.336). Most subjects replied ‘never’ when asked if the ring had interfered with their daily activities, similar, with no difference between products (p=0.904). Only 17 subjects had sexual intercourse during the study, and no differences were seen between products in reporting of discomfort or whether the ring could be felt by their partner (p=1.000 and p=0.275, respectively). The dynamometer results were showed similar flexibility on both rings.

Conclusions:

Ornibel® is a new generation of contraceptive vaginal ring, bioequivalent in efficacy and safety to reference product with a very well tolerated profile. The acceptability of the ring could be shown in these first clinical data

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