

# DTB CME/CPD Answers



Drug and Therapeutics Bulletin

## ▼ Jaydess IUS

### Question 1

Ms LV, aged 25 years, is considering using a levonorgestrel-releasing intra-uterine delivery system (IUS) following the birth of her first child. In the UK, approximately what percentage of women who are of reproductive age use some form of contraception?

- a. 45%
- b. 55%
- c. 65%
- d. 75%
- e. 85%

Answer: d. In the UK, around 75% of women of reproductive age use some form of contraception.

### Question 2

Ms LV discusses her options with her family-planning nurse and asks about levonorgestrel-containing IUS products. Which one of the following statements about the Jaydess IUS is correct?

- a. It is recommended that postpartum insertions should be delayed until 3 weeks after delivery
- b. It has been recommended by the National Institute for Health and Care Excellence as a first-choice contraceptive in parous and nulliparous women
- c. It is designed to have the same daily release rate of levonorgestrel as the Mirena IUS
- d. It is licensed for contraception for up to 5 years
- e. It has a smaller frame and narrower insertion tube than the Mirena IUS

Answer: e. The Jaydess IUS has a smaller frame, narrower insertion tube compared with the Mirena IUS.

### Question 3

The European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has published guidance on the requirements for the statistical analysis of the Pearl Index. Key studies should be large enough to give the overall Pearl Index with a two-sided 95% confidence interval (CI) such that the difference between the upper limit of the confidence interval and the point estimate does not exceed what value?

- a. 0.1
- b. 0.5
- c. 1.0
- d. 1.5
- e. 2.0

Answer: c. Key studies should be large enough to give the overall Pearl Index with a two-sided 95% confidence interval such that the difference between the upper limit of the CI and the point estimate does not exceed 1.

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### Question 4

Jaydess IUS has been evaluated in a single phase 3 clinical trial involving 2,885 women aged 18–35 years, and a supportive phase 2 trial involving 742 women aged 21–40 years. Which one of the following statements about the studies is correct?

- In the Jaydess IUS group of the phase 3 trial, the unadjusted Pearl Index was 0.33 (95% CI 0.16 to 0.60) at 3 years
- The phase 2 trial demonstrated non-inferiority of Jaydess IUS against the Mirena IUS
- In the phase 3 trial, 87% of women in the Jaydess IUS group completed the planned treatment duration of 3 years
- In the phase 3 trial, the first insertion attempt was successful in 90% of instances in the Jaydess IUS group
- In the phase 2 trial, the Kaplan-Meier estimates for the cumulative failure rate over 3 years were 0.3% for the Jaydess IUS and 0.2% for the Mirena IUS

Answer: a. The unadjusted 1-year Pearl index was 0.41 (95% CI 0.13 to 0.96), and after 3 years was 0.33 (95% CI 0.16 to 0.60) in the Jaydess group of the phase 3 trial.

### Question 5

Ms LV asks her family-planning nurse about possible adverse effects associated with Jaydess IUS. Which one of the following statements regarding the safety analysis of the phase 2 and phase 3 trials of Jaydess IUS is correct?

- The absolute rate of ectopic pregnancy in Jaydess IUS users was 0.2% over 3 years use
- Acne, breast discomfort and abdominal pain were among the most common adverse events associated with study discontinuation
- The adverse event profile of the Jaydess IUS is generally consistent with all other long-acting reversible contraceptives
- The overall rate of pelvic inflammatory disease was 4% in the Jaydess IUS group and occurred mainly in nulliparous women
- Serious adverse events occurred in around 10% of women in the Jaydess IUS group

Answer: a. A total of four ectopic pregnancies occurred during treatment with Jaydess (pooled data), equating to an absolute ectopic pregnancy rate of 0.2% over 3 years' use.