

DTB CME/CPD Answers



Drug and Therapeutics Bulletin

Does alprostadil cream hit the spot?

Question 1

The erectile function domain of the International Index of Erectile Function (IIEF-EF) score is commonly used as the primary outcome in clinical trials of drugs for erectile dysfunction. What increase in IIEF-EF score is generally considered to be clinically relevant?

- a. ≥ 1 point
- b. ≥ 4 points
- c. ≥ 8 points
- d. ≥ 15 points
- e. ≥ 25 points

Answer: b. The International Index of Erectile Function (IIEF) is the standard tool for evaluating the efficacy of drugs for treating erectile dysfunction. The erectile function (IIEF-EF) score is the primary measurement domain of the IIEF and is a commonly used primary outcome measure in clinical trials of drugs used to treat erectile dysfunction. A score above 25 indicates normal erectile function; an increase of at least 4 points on this score is generally considered to be clinically relevant.

Question 2

First-line drug therapy for erectile dysfunction is normally an oral phosphodiesterase (PDE) type-5 inhibitor. In what proportion of men with erectile dysfunction are PDE-5 inhibitors effective?

- a. 15%
- b. 25%
- c. 45%
- d. 60%
- e. 75%

Answer: e. First-line drug therapy for erectile dysfunction is normally an oral PDE type-5 inhibitor (▼avanafil, sildenafil, tadalafil or vardenafil). PDE-5 inhibitors facilitate rather than initiate erections and are effective in 75% of men (vs. 46% with placebo).

Question 3

According to guidelines from the British Society for Sexual Medicine, how many doses of a PDE-5 inhibitor at maximum dose should be used before a patient is classified as a non-responder?

- a. 2
- b. 4
- c. 8
- d. 18
- e. 24

Answer: c. Around 30–40% of men do not respond sufficiently to PDE-5 inhibitors, but some of these may be due to incorrect use of the medication and they may be helped through counselling. British Society for Sexual Medicine guidelines recommend that men should have used eight doses of PDE-5 inhibitors at maximum dose with sexual stimulation before being classified as a non-responder.

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Question 4

Alprostadil cream has been evaluated in two double-blind placebo-controlled trials involving 1,732 men with mild to severe erectile dysfunction, and one 9-month open-label trial involving 998 men from the placebo-controlled trials and 163 additional men who had not used alprostadil cream. Which one of the following statements about the studies is correct?

- In the double-blind placebo-controlled trials compared with placebo the mean change in IIEF-EF score was statistically significant for alprostadil 300µg but not 200µg
- In the double-blind placebo-controlled trials, overall mean IIEF-EF score at the end of the trial was greater than 25 in men using alprostadil cream
- In the double-blind placebo-controlled trials, penetration success but not mean ejaculation success was significantly improved in men using alprostadil cream compared with placebo ($p < 0.001$ for all doses)
- In the double-blind placebo-controlled trials, around 40% of responders achieved a clinically significant improvement of IIEF-EF score with alprostadil 200µg or 300µg
- In the final analysis of 141 patients from the open-label trial, mean change in IIEF-EF score from baseline to 180 days was 2.5 with alprostadil 200µg, and 5 with 300µg

Answer: d. An analysis of responders in the trial population presented in the Public Assessment Report (which summarises the regulatory decision) indicated that around 40% of patients achieved a clinically significant improvement of IIEF-EF score with alprostadil 200µg or 300µg cream.

Question 5

Which one of the following statements regarding the safety of alprostadil cream is incorrect?

- Priapism has been reported in up to 0.4% of men using alprostadil cream in clinical trials
- Alprostadil cream may cause vaginal irritation
- Skin rash, penile burning, tingling or pain are reported in up to 10% of men using alprostadil cream
- Only latex based condoms have been investigated together with alprostadil
- Human studies have shown reversible degeneration of the seminiferous tubules of the testes after repeated dosing with alprostadil cream

Answer: e. Studies in rabbits showed reversible degeneration or atrophy of the seminiferous tubules of the testes after repeated dosing with alprostadil cream.