

## ▼ Naloxegol for opioid-induced constipation

### Question 1

What is the estimated incidence of opioid-induced constipation in patients taking opioids for non-malignant pain?

- a. 10–20%
- b. 20–40%
- c. 40–60%**
- d. 60–80%
- e. 80–90%

**Answer: c.** The incidence of opioid-induced constipation ranges from 40–60% of patients taking opioids for non-malignant pain and 60–90% of those with cancer related opioid use.

### Question 2

Which one of the following statements regarding opioid-induced constipation is correct?

- a. It is thought that around 25% of patients with cancer receiving long-term opioid treatment will experience severe constipation that does not respond to treatment with laxatives
- b. Laxatives can adequately treat approximately 50% of patients with opioid-induced constipation**
- c. Activation of central delta receptors accounts for the main constipatory effect of opioids
- d. For most people opioid-induced constipation is a transient problem to which tolerance develops
- e. Initial treatment of opioid-induced constipation should be with a bulk-forming laxative

**Answer: b.** When used appropriately laxatives can adequately treat at least 50% of patients with opioid-induced constipation.

### Question 3

Naloxegol, a derivative of naloxone, is licensed for opioid-induced constipation in adult patients who have had an inadequate response to laxative treatment. Which one of the following statements regarding naloxegol is correct?

- a. Naloxegol is primarily eliminated by renal excretion
- b. Maintenance laxative therapy should be continued during the first 4 weeks of naloxegol therapy
- c. The presence of a polyethylene glycol group (PEGylation) reduces the permeability of naloxegol across the blood-brain barrier**
- d. Naloxegol is only licensed for patients who have not responded to two classes of laxative for at least 7 days during the previous 4 weeks
- e. The recommended dose is 25mg twice a day

**Answer: c.** Naloxegol is a derivative of the  $\mu$ -opioid antagonist naloxone to which has been added a polyethelene glycol group (PEGylation) to reduce permeability across the blood-brain barrier.

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### Question 4

Two identical placebo-controlled trials evaluated the efficacy of naloxegol in patients with opioid-induced constipation over 12 weeks. Which one of the following statements regarding these studies is correct?

- a. Patients had been receiving oral or parenteral morphine for at least 8 weeks
- b. The study excluded patients with a diagnosis of cancer within the last 5 years
- c. At least 75% of patients were defined as 'laxative inadequate responders'
- d. The primary outcome was 4 or more spontaneous bowel movements per week
- e. Maintenance treatment with regular laxative therapy was permitted

Answer: b. Patients with uncontrolled pain, a diagnosis of cancer within the last 5 years, conditions or use of medicines associated with diarrhoea or constipation, or evidence of gastro-intestinal obstruction or other conditions associated with an increased risk of bowel perforation were excluded.

### Question 5

What was the absolute increase in the primary endpoint for the 25mg dose of naloxegol compared with placebo for the subgroup of laxative inadequate responders in both trials?

- a. 49% and 29%
- b. 43% and 31%
- c. 35% and 20%
- d. 27% and 21%
- e. 20% and 15%

Answer: e. The absolute increase in response rate for laxative inadequate responders was (48.7%–28.8%) and (46.8%–31.4%).