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Bowel cleansers: serious adverse effects

● **Gastritis, hyponatraemia**

Preparations containing phosphate salts are used to prepare the colon for surgery or colonoscopy. The French Health Products Agency (ANSM) published a review of 185 adverse drug reactions attributed to Colokit° tablets that were reported in France between September 2010 and December 2012 (1,2).

The ANSM considered 35 of the adverse effects serious: 15 were gastrointestinal, 5 cardiac, 3 renal, 2 allergic, one neurological, and 9 were electrolyte disorders. The other adverse effects were mainly gastrointestinal (137 cases), allergic (8 cases) and neurological (3 cases) disorders.

Cases of severe hyponatraemia (113 to 127 mmol/l) were reported, sometimes causing neurological disorders. Electrolyte disorders were probably a contributory factor in the reported cases of atrial fibrillation.

Gastritis was the commonest serious gastrointestinal disorder, often erosive or necrotic, and sometimes ulcerated. Cases of erosive or ulcerated colitis were also reported, most of which were not serious.

Several acute hypersensitivity reactions (urticaria, angioedema and anaphylactic shock) were attributed to macrogol, one of the excipients.

Bowel cleansers expose patients to sometimes serious adverse effects. These should be taken into account when weighing the benefits of colonoscopy against its harms.

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Selected references from Prescrire's literature search.

1- ANSM "Réunion du comité technique de pharmacovigilance - suivi national de pharmacovigilance Colokit° (phosphate monosodique monohydrate, phosphate disodique anhydre)" 18 March 2013. ansm.sante.fr accessed 23 August 2013: 3 pages.

2- Prescrire Rédaction "phosphates de sodium comprimés-Colokit°. Pas d'avantage décisif par rapport à la solution buvable" *Rev Prescrire* 2011; **31** (329): 175.

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Fentanyl patches: deaths in children

● **Safe disposal of used patches is a must**

In August 2013, following the death of a 15-month-old infant, the U.S. Institute for Safe Medication Practices (ISMP) issued a reminder on the danger that the *fentanyl* patch represents for children (1). The child was napping on his sleeping mother's chest. When the mother awoke, her son was unconscious. The *fentanyl* patch she had applied for pain associated with multiple sclerosis was no longer on her chest and could not be found, having probably been swallowed by the infant. Toxicological studies confirmed acute *fentanyl* intoxication.

A 2-year-old boy died after he swallowed a used patch while playing in his grandmother's room in a long-term care facility (1).

In April 2012, the US Food and Drug Administration (FDA) reported 26 cases of accidental exposure to *fentanyl* since 1997, most of which involved children under the age of 2. Ten children died and an additional 12 cases required hospitalisation (2). Healthcare professionals have an important role in preventing accidental exposure of young children to *fentanyl* patches. Information and practical advice must be adapted to each situation; this must include the disposal of used devices, which still contain large amounts of *fentanyl* (3).

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Selected references from Prescrire's literature search.

1- Institute for Safe Medication Practices (ISMP) "Fentanyl patch fatalities linked to "bystander apathy". We all have a role in prevention" *ISMP Medication Safety Alert* 2013; **18** (16): 1-4.

2- FDA "Fentanyl patch can be deadly to children" FDA Consumer Health Information, April 2012. www.fda.gov accessed 23 August 2013: 2 pages. (see note above)

3- Prescrire Editorial Staff "Fentanyl patches: preventable overdose " *Prescrire Int* 2010; **19** (105): 22-25.

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Zolpidem: next-morning residual effects

● **No safer than benzodiazepines**

Zolpidem was first marketed in the late 1980s. At that time, several studies were presented claiming it has a short half-life and does not decrease alertness the next morning. *Zolpidem*'s minimal effect on alertness was supposed to distinguish it from the benzodiazepines, with which it shares many similarities (1).

In January 2013, the US drug regulatory agency (FDA) reported that, in some patients, after taking *zolpidem* in the evening, the residual plasma concentration the next morning is high enough to reduce alertness and impair activities such as driving. The FDA was aware of 700 reports of road traffic accidents or impaired driving ability associated with *zolpidem* use (2).

This is yet another example of a drug that was portrayed as "safe" when first marketed, supported by an initial evaluation including about ten studies on residual effects in healthy volunteers. Over time, *zolpidem*'s claimed advantages over benzodiazepines are disappearing. *Zolpidem* exposes patients to the risk of dependence and abuse, drowsiness and automatic behaviours, and residual effects provoking road traffic accidents, just like benzodiazepines (3,4).

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Selected references from Prescrire's literature search.

1- Prescrire Rédaction "Stilnox°" *Rev Prescrire* 1988; **8** (29): 426-427.

2- U.S. Food and Drug Administration "Questions and answers: risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist)" 10 January 2013. www.fda.gov accessed 27 August 2013: 3 pages.

3- Prescrire Editorial Staff "Hypnotic dependence: zolpidem and zopiclone too" *Prescrire Int* 2001; **10** (51): 15.

4- Prescrire Editorial Staff "Zolpidem: sleepwalking and automatic behaviours" *Prescrire Int* 2007; **16** (91): 200.