

Loperamide: Reports of serious cardiac adverse reactions with high doses, associated with abuse or misuse

Background:

- At extremely high concentrations, loperamide has the potential to slow cardiac conduction via inhibition of sodium channels, and produce conduction arrhythmias.
- QT prolongation or torsades de pointes were recorded with daily dosages ranging from 40-80 mg up to 800 mg (the recommended maximum daily dose is 16 mg).
- High doses of loperamide may be prescribed under specialist recommendation for high output stoma, where the benefit outweighs the risk.

Advice for healthcare professionals:

- When prescribed in primary care, or purchased over the counter, healthcare professionals are reminded that if symptoms of overdose occur, naloxone can be given in secondary care as an antidote.
- When purchased over the counter, pharmacists should remind patients not to take more than the recommended dose on the label.

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Solu-Medrone 40 mg may contain trace amounts of milk proteins

Do not use in patients with a known or suspected allergy to cows' milk (serious allergic reactions have been reported)

Background:

Solu-Medrone 40 mg uses lactose produced from cows' milk as an excipient and may contain trace amounts of milk proteins. Other strengths of Solu-Medrone do not currently contain lactose.

Advice for healthcare professionals:

If a patient's symptoms worsen or any new allergic symptoms occur, allergic reaction to cows' milk proteins should be suspected; stop administration of the product and treat the patient's condition accordingly.

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Miconazole (Daktarin): Oral gel prescribed or purchased as a pharmacy only (P) medicine, contraindicated in patients taking warfarin

Advice for healthcare professionals:

- Patients taking warfarin should not use ANY miconazole oral gel.
- If the concomitant use of prescribed or purchased miconazole oral gel, with an oral anticoagulant such as warfarin is planned, exercise caution and ensure that you monitor and titrate the anticoagulant effect carefully, noting the licensing contraindicates concomitant use.
- Advise patients taking prescription-only miconazole oral gel and warfarin, that if they experience signs of over-anticoagulation, such as sudden unexplained bruising, nosebleeds, or blood in urine, they should stop using miconazole and seek immediate medical attention.

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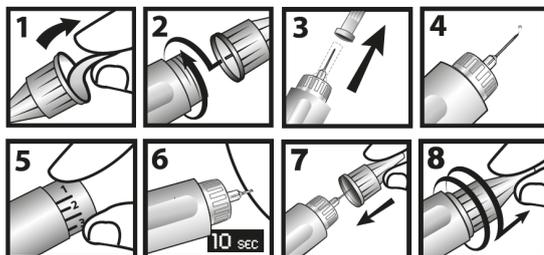
Remember; always report ANY suspected adverse reactions to the MHRA [Yellow Card Scheme](#).

Field Safety Notice: Microdot Droplet Pen Needle 4mm x 32G, type 810, cat number 8065

The current instructions for use (IFU) shows 6 steps on use of the device. The steps on how to remove and put on the needle caps are not included.

Advice for healthcare professionals:

If a patient reports as having needles "bent and unsafe to use", the most likely cause is the incorrect removal or multiple recapping of the needle cap. Health professionals should reinforce the correct technique as per the [updated IFU](#).



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Recombinant human erythropoietins (r-HuEPOs): Risk of severe cutaneous adverse reactions (SCARs)

Background:

- r-HuEPOs include: darbepoetin alfa, epoetin alfa, epoetin beta and epoetin zeta.
- Cases of SCARs have been reported rarely in patients treated with r-HuEPOs. These included cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some of which have been fatal.
- SCARs are considered to be a class effect of all r-HuEPOs.
- The reactions have been more severe with long-acting r-HuEPOs.

Advice for healthcare professionals:

- Patients starting treatment with an r-HuEPO product, who develop the following signs and symptoms (widespread rash with reddening and blistering of the skin and oral mucosa, eyes, nose, throat, or genital area, which follow flu-like symptoms including fever, tiredness, muscle and joint pain, this often leads to peeling and shedding of the affected skin which looks like a severe burn should be instructed to contact their doctor immediately and stop epoetin treatment.
- If the patient has developed SCARs, such as SJS or TEN, which is considered to be related to the use of an r-HuEPO the patient must never be given an r-HuEPO again.

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Remember; always report ANY suspected adverse reactions to the MHRA [Yellow Card Scheme](#).

Clozapine (Clozaril, Denzapine, Zaponex): Reminder of potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

Clozapine has been associated with varying degrees of impairment of intestinal peristalsis. The effects can range from constipation, which is very common, to intestinal obstruction, faecal impaction, and paralytic ileus, which are very rare. On a few occasions, cases have been fatal.

Advice for healthcare professionals:

- Clozapine is a hospital only medicine; ensure this is recorded in the patients record on [SystemOne](#).
- Clozapine is contraindicated in patients with paralytic ileus.
- Advise patients to report constipation immediately.
- Actively treat any constipation that occurs.
- Exercise particular care in patients receiving other drugs known to cause constipation (especially those with anticholinergic properties), patients with a history of colonic disease or lower abdominal surgery, and in patients aged 60 years and older.

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Isotretinoin (Roaccutane): Rare reports of erectile dysfunction and decreased libido, in patients taking oral isotretinoin, indicated for severe acne

Advice to healthcare professionals:

- Isotretinoin is a hospital only medicine; ensure this is recorded in the patients record on [SysmOne](#).
- Be aware of rare reports of sexual side effects, including erectile dysfunction and decreased libido.
- One possible mechanism for this effect may be through a reduction in plasma testosterone levels.
- Consult the Summaries of [Product Characteristics \(SPCs\) for isotretinoin](#).

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