HYDROMorphine (high-risk medicine): Changes to Dilaudid® injectable preparations

Background
HYDROMorphine is a potent opioid analgesic frequently used to treat moderate to severe, acute or chronic pain. HYDROMorphine is 5 to 7 times more potent than morphine. Because of its high potency, errors with this medicine may result in serious adverse patient outcomes, including deaths.

This Safety Alert highlights significant changes to HYDROMorphine injectable preparations (Dilaudid® and Dilaudid® HP injections) and advises actions in addition to Safety Alert 001/17 HYDROMorphine: High-risk medicine.

NEW Dilaudid® HP 50 mg in 1 mL injection
The NEW presentation Dilaudid® HP 50 mg in 1 mL ampoule injection is highly potent. It is five times the concentration of the discontinued 50 mg in 5 mL ampoule. The inadvertent injectable bolus administration of 1 mL containing 50 mg of HYDROMorphine (equivalent to 250 to 350 mg of injectable morphine) is likely to result in a fatal outcome.

Hospitals must NOT include Dilaudid® HP 50 mg in 1 mL injection on their hospital formulary or hold inventory stock of this product.

Similar appearances of Dilaudid® injections
The similar look-alike clear glass ampoules of all new presentations of HYDROMorphine ampoules increase the risk of product selection errors.

Hospitals should consider stocking only one strength (either the 2 mg in 1 mL or the 10 mg in 1 mL Dilaudid) of HYDROMorphine injection in ward areas where HYDROMorphine is stored. If both strengths are stocked (e.g. in pharmacy), risk mitigation strategies must be put in place to minimise incidents associated with incorrect product selection.

Examples of risk mitigation strategies include storing the products in separate locations; affixing warning labels on the products and storage bins; and where high doses are required, hospitals should consider sourcing manufactured pre-filled products.

Immediate Actions required by Local Health Districts/Networks
In addition to the actions set out in Safety Alert 001/17:

1. Distribute this Safety Alert to all relevant clinical staff.
2. Confirm that Dilaudid® HP 50 mg in 1 mL injection will NOT be included on the hospital formulary and inventory stock of this product will NOT be held.
3. Consider keeping only one strength of HYDROMorphine injection, in ward areas where HYDROMorphine injections are routinely stocked (e.g. palliative care).
4. Implement strategies to minimise product selection errors when more than one strength is stocked (e.g. in pharmacy).
5. Restrict availability of HYDROMorphine 10 mg in 1 mL injection within the hospital.
6. Consider sourcing manufactured pre-filled products for clinical areas where high doses may be required.
8. Acknowledge the receipt of the Safety Alert within 48 hours.