Curbing med errors involving Anzemet, Bentyl

Problem: Potential medication errors have been reported involving the total drug content contained in each Anzemet (dolasetron mesylate injection, Aventis) ampule. The Anzemet ampule is labeled as 12.5 mg (20 mg/mL), leading healthcare practitioners to believe that the ampule contains 20 mg or 1 mL of dolasetron, when in fact the ampule contains 12.5 mg or 0.625 mL. Healthcare practitioners are concerned that underdosing may result from this confusing expression of strength. Postmarketing experience has demonstrated serious medication errors resulting from other small-volume parenteral drug products that are not labeled with their total drug content.

Anzemet is indicated in the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin; the prevention of postoperative nausea and vomiting; and the treatment of postoperative nausea and/or vomiting. Anzemet is commercially available in a tablet and intravenous formulation. Patients needing treatment of nausea and vomiting associated with cancer chemotherapy are dosed on a mg/kg basis; patients with postoperative nausea and/or vomiting require a single dose of 12.5 mg of Anzemet. A miscalculation of the dosage could result in a failure to achieve a therapeutic dose, possibly resulting in unnecessary patient discomfort.

The table summarizes the medication error reports received by the Food & Drug Administration since February 1999; two were received in 2001, one in 2000, one in 1999. All reports were classified as potential errors.

Recommendation: The FDA has recommended several labeling interventions that might minimize user error. The most important is that the labels be revised to accurately reflect the total drug content of each ampule as 12.5 mg/0.625 mL.

Postmarketing safety reports of medication errors associated with Anzemet labeling

Chief complaint	Abbreviated narrative
Light color and small print size	The ampule label is difficult to read because of the light print color and small print size. NDC is not on the label.
Small print; label is very confusing	Anzemet 12.5 (20 mg/mL): very small print size states 0.625 mL. It is difficult to determine that the vial contains 0.625 mL of solution and 12.5 mg of Anzemet. There is a high potential of undermedicating the patient by drawing up only half of vial.
Confusing label	Anzemet injection ampule is 20 mg/mL. However, ampule contains only 0.625 mL or 12.5 mg. High risk for confusion exists.
Confusing label	Anzemet 12.5-mg ampule for injection is causing confusion due to the bold print on the package, which reads 20 mg/mL, while the small print indicates it is 0.625 mL (12.5 mg).

Problem: Two types of errors involving Bentyl (dicyclomine hydrochloride injection, Aventis) have been identified. First, nine postmarketing medication error reports involved cases of inadvertent administration of Bentyl by the intravenous route, rather than by the intended intramuscular route. One of these errors resulted in permanent disability; other case reports describe episodes of bradycardia, dizziness, and dry mouth. While the carton labeling clearly states, FOR INTRAMUSCULAR USE ONLY, the container label does not provide a similar warning. Carton labeling is often discarded to provide for ample storage space on pharmacy shelves and patient care areas.

Second, 24 medication error reports were received relating to confusion over the total drug content contained in each 2-mL Bentyl ampule. The ampules are currently labeled as 10 mg/mL. However, the net quantity appears in conjunction with this statement, leading healthcare practitioners to believe that each ampule provides 10 mg, when in fact each ampule contains 20 mg. Four of the 24 reports involving confusion over the total drug content resulted in the administration of 40 mg rather than the intended 20 mg. There were no serious adverse events resulting from the drug overdoses.

The manufacturer, Aventis Pharmaceuticals Inc., is currently revising the container labels and carton labeling to clarify the total drug content and to provide a warning statement on the container label that states that the product is intended for "intramuscular use only." In the interim, see the safe practice recommendations below.

Recommendation: Whenever possible, store Bentyl injection in the original carton, and do not remove the ampules from the outer carton until the time of use. In addition, prior to dispensing and administration of Bentyl injection, inform the healthcare provider that the ampule contains 20 mg (2 mL) and is intended *for IM administration only*. This can be achieved by placing each ampule in a separate package (e.g., plastic bag or envelope) that is affixed with an appropriate pharmacy label.

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MEDWATCH

To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.