Acetylcysteine Oral Solution Mistaken for Parenteral Use

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Problem: Several companies manufacture and distribute acetylcysteine solution (Abbott, American Regent, Bedford, Dey, Faulding, Gallipot, Medisca, Meridian, and Roxanne). It is available in 10% and 20% solutions and packaged in 4-, 10-, and 30-mL glass vials. The drug can be diluted and administered parenterally for some off-label uses in the U.S. (e.g., acetaminophen poisoning), but for all approved indications, it is to be administered via inhalation or orally (diluted to mask the taste). However, the vials, particularly the smaller ones, look similar to those that contain an injectable product. They even have a target area on the rubber stopper. The label states “not for injection,” but the message is small and, depending on the manufacturer, might not be located below or near the drug name.

The Institute for Safe Medication Practices (ISMP) received an error report in which a patient was ordered 17 doses of acetylcysteine and halfway through therapy, because of the taste, the patient asked if there was an alternative method for receiving the medication. The nurse supposedly looked at the vial and gave the drug intravenously (IV) because it appeared to be an injectable product.

Another report reveals that a pharmacy dispensed acetylcysteine 4-mL vials in an individual patient bag with an appropriate label stating “to be given orally.” The nurse withdrew the dose (600 mg = 3 mL) and injected the patient with the dose. The error was discovered when the patient asked the critical care nurse, “When am I going to get that awful tasting medication?” and the nurse stated, “Don’t worry, I gave the medication IV.” The patient did not experience any adverse effects.

In addition, some companies label the strength as a percentage, such as a 20% solution for inhalation, but do not provide a mg/mL concentration on the labeling. When the physician orders the drug in “mg” for this indication, there is an increased risk of error without a corresponding “200 mg/mL” comment on the label of the 4-mL vials. For example, ISMP received a report stating that a nurse who went to administer the medication did not know what the concentration of a 20% solution was. She had no idea that 20% was the same as 200 mg/mL, but she called the pharmacy to clarify, so the patient received the appropriate dose.

Last year, a study showed that hydration and prophylactic oral administration of acetylcysteine prevents reduced renal function caused by contrast agents in patients with chronic renal insufficiency.1 As a result of this new use, nurses who were previously unfamiliar with the drug might now be administering it in various patient-care settings, including cardiac-care units, where patients often have IV access. Recently, we learned of three such errors with this product. In one case, acetylcysteine was almost administered IV. The error was caught when the nurse called a pharmacist to question compatibility with the patient’s existing IV fluids. In the two other cases, a pharmacy dispensed an acetylcysteine 4-mL vial with a label stating, “to be given orally.” The nurse, who thought she was drawing up an injection, withdrew the doses and injected the patients. Fortunately, the patients did not experience adverse effects.

Safe Practice Recommendations: If acetylcysteine is used for indications outside of respiratory treatments, it should be dispensed from the pharmacy. The pharmacy should dispense patient-specific oral syringes, but if the volume of medication needed for each dose to treat acetaminophen poisoning exceeds the capacity of oral syringes, the pharmacy should remove the medication from the manufacturer’s container and place the proper dose in an oral solution bottle with a clear label designating the drug, dose, and route of administration. Harm can result if the drug is administered undiluted via IV administration. ISMP has notified the FDA about the label issues. One manufacturer recently informed ISMP that the label and print size will be enlarged, and will include the warnings “for inhalation” and “not for injection.” However, they have no plans to change the vial configuration at this time.

Reference