MEDICATION ERRORS

Life-Threatening Errors With Flecainide Suspension in Children
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Flecainide is an oral class IC antiarrhythmic drug that may be used to treat atrial fibrillation or supraventricular tachycardia, particularly when conventional treatment agents fail. Because it is available commercially only as 50-mg, 100-mg, and 150-mg tablets, it must be compounded into a suspension when needed for infants and small children. Unfortunately, errors during preparation and dosing of the suspension have occasionally led to serious overdoses that resulted in cardiac emergencies and required immediate therapeutic intervention. Overdoses can lead to seizures and cardiotoxicity, including ventricular tachycardia and fibrillation due to sodium-channel blockade. Treatment includes sodium bicarbonate boluses or sodium chloride boluses and extracorporeal circulatory support.

The Institute for Safe Medication Practices (ISMP) first learned of a flecainide suspension-related error from a report submitted in 2007. A 4-month-old infant had been receiving 8 mg twice daily as an 8-mg/mL suspension (1 mL per dose). When the dose was later increased to 10 mg, a suspension purported to be 10 mg/mL was compounded. However, the baby’s mother complained that the suspension was too thick to withdraw from the bottle. The pharmacist asked the mother to return the suspension and elected to compound a 7-mg/mL suspension, instructing the parent to give 1.4 mL per dose. Due to a math error, this replacement suspension was actually compounded with 6 g (6,000 mg) of flecainide instead of 600 mg; therefore, each dose represented 100 mg, not 10 mg. It is unclear whether the previous 10-mg/mL suspension may also have been prepared incorrectly.

Additional errors with compounded flecainide suspension have appeared in the literature. A 2-year-old child received a fivefold overdose when unlabeled oral syringes of nadolol and flecainide were used. Instead of withdrawing 5 mL of nadolol suspension (concentration not specified) and 1 mL of flecainide suspension (20 mg/mL), the nurse administered the opposite, and the child received 5 mL of flecainide (100 mg). In another case, a pharmacy dispensed a 5-mg/mL suspension for a 4-week-old child who was supposed to receive 3 mg/0.6 mL three times a day. Pharmacy staff erroneously transcribed the dosing instructions to take “3 mL” instead of 3 mg (0.6 mL), resulting in an overdose that led to wide complex tachycardia. In a third case, an 18-day-old infant received four doses of flecainide 8 mg (0.8 mL of a 10-mg/mL suspension) instead of 4 mg (0.8 mL of a 5-mg/mL suspension), also resulting in wide complex tachycardia and cardiac arrest from which the child recovered. A fourth case involved a 9-month-old infant whose parents were told to increase the dose of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription. But the parents refilled the prescription at another pharmacy, receiving the drug in a 20-mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation. Finally, an event published in 2014 described an error in which the aunt of a 7-month-old child unknowingly gave her nephew a fivefold overdose of flecainide. She pulled the suspension into an oral syringe that had both a teaspoon and mL scale and measured 5 mL (one teaspoon) instead of 1 mL. The child was hospitalized and suffered a cardiac arrest but was successfully resuscitated. Fortunately, all of the children recovered without neurological sequelae following life-threatening flecainide overdoses.

Unrecognized changes in drug concentration, math errors, labeling errors, and inaccurate dosing instructions led to the confusion in these cases. In one case, the authors indicated that all of their local pharmacies had agreed to compound flecainide in one standard concentration of 20 mg/mL. Along this line, a Michigan statewide initiative agreed to standardize the flecainide concentration and other compounded liquid medication concentrations for pediatric patients. The initiative provides the preparation directions, final concentration, stability data, storage information, and information for prescribers and families about the standards. Such efforts to standardize concentrations in both inpatient and outpatient pharmacies can help eliminate medication errors like those described above. The American Society of Health-System Pharmacists, in cooperation with ISMP, the Food and Drug Administration, and other stakeholders, is trying to broaden this initiative nationwide.

To reduce the risk of errors, prescribers should order flecainide in terms of the mg dose. This allows pharmacists to address the suspension concentration (mg/mL) and volume per dose, which should be expressed in mL (metric). For neonates and infants, a lower concentration may be required. If the drug is prescribed by volume (mL), the concentration must be specified, or the prescriber must be contacted for clarification.

In hospitals, pharmacy labels should specify the dose in terms of both mg and mL, followed by the concentration, such as “Flecainide 5 mg (0.25 mL) 20 mg/mL suspension.” The pharmacy should dis

continued on page 286
Medication Errors

continued from page 258

pense all doses in patient-specific oral syringes. In ambulatory care, when dispensing the medication, the retail pharmacy should provide liquid suspensions with a flow restrictor embedded in the neck of the bottle (Figure 1) along with an oral syringe to measure and administer doses. Be sure to remind the patient or parents to secure the child-resistant cap after each use. Label directions should include the dose in terms of mL, such as “Flecainide 0.25 mL by mouth every 8 hours.” The community pharmacy label should also include the concentration next to the drug name, below the instructions for use. To be sure parents give a proper dose, use “teach-back” methods to demonstrate how to measure and administer proper amounts. This also gives pharmacists and parents an opportunity to catch an error.

REFERENCES


The reports described in this column were received through the ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the ISMP website (www.ismp.org) or communicated directly to ISMP by calling 1-800-FAILSAFE or via email at ismpinfo@ismp.org.