FDA Drug Safety Communication: Serious medication errors from intravenous administration of nimodipine oral capsules

Safety Announcement

[08-02-2010] The U.S. Food and Drug Administration (FDA) is alerting healthcare professionals that nimodipine capsules should be given ONLY by mouth or through a feeding tube (nasogastric tube). This oral medication should NEVER be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage (ruptured blood vessels in the brain) and is only available as a capsule. In 2006, FDA added a Boxed Warning and made other revisions to the prescribing information to warn against intravenous use of nimodipine. The prescribing information also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use."

FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

Additional Information for Patients

- FDA encourages all patients to talk to their healthcare professional if they have concerns about any treatment they are receiving.
- Report any side effects from the use of medication to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page.

Additional Information for Healthcare Professionals

- Be aware that nimodipine should be administered ONLY by the oral route or via nasogastric tube. It should NEVER be administered intravenously.
- If the nimodipine capsule cannot be swallowed, e.g., at the time of surgery, or if the patient is unconscious, a hole should be made in both ends of the capsule with an 18 gauge needle, and the contents of the capsule extracted into a syringe. To help minimize administration errors, it is recommended that the syringe be labeled "Not for IV Use." The needle should be removed from the syringe and the contents should then be emptied into the patient's in situ nasogastric tube and washed down the tube with 30 mL of normal saline (0.9%).
- Report adverse events or medication errors involving nimodipine capsules to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of this page.

Data Summary

Since the approval of nimodipine in 1988, FDA has taken several actions intended to reduce the
occurrence of inappropriate intravenous use of this drug. In 1996, a bolded statement was added to the prescribing information to warn against incorrect administration of nimodipine. In 2006, FDA added both a Boxed Warning and a Warning to the nimodipine labeling to alert practitioners not to administer nimodipine intravenously or by other parenteral routes, and described the potential for fatal and life-threatening adverse effects following erroneous parenteral nimodipine administration. FDA also revised the Dosage and Administration section regarding administration of the capsule contents to patients who are unable to swallow.

FDA identified 31 cases of medication errors associated with the use of nimodipine that were reported to FDA’s Adverse Event Reporting System (AERS), the Pennsylvania Patient Safety Reporting System (PA-PSRS), the Institute for Safe Medication Practices’ (ISMP) Quantros MEDMARX database, and the Council for International Organizations of Medical Sciences (CIOMS) II database, and published in the medical literature between 1989 (initial marketing of nimodipine) and 2009. Of the 31 medication errors, 25 involved erroneous intravenous nimodipine prescribing or administration. Four of the patients who mistakenly received nimodipine intravenously died; five patients were characterized as having near-death events; and one patient was characterized as having suffered permanent harm as a result of the inadvertent intravenous administration of nimodipine.

Based on FDA’s review of these reports, the following factors have been identified as contributing to this preventable medication error:

- Since some patients receiving nimodipine cannot swallow the capsules, they must receive the liquid from the capsules through a feeding tube. The nimodipine prescribing information has instructions for using a needle to make a hole in both ends of the capsule to remove the liquid contents with a syringe and then empty the contents into the feeding tube. Because a standard needle will not fit on an oral syringe, the needle must be attached to an intravenous syringe. The use of intravenous syringes to deliver nimodipine increases the chance that the medication will be given intravenously instead of by mouth or nasogastric tube.
- Most patients receiving nimodipine are hospitalized in critical care units and are already receiving intravenous medications.

Related Information

- Nimodipine Information

Contact FDA
1-800-332-1088
1-800-FDA-0178 Fax
Report a Serious Problem
MedWatch Online

Regular Mail: Use postage-paid FDA Form 3500
Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20857

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