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SERIOUS MEDICATION ERRORS CONTINUE FROM INTRAVENOUS ADMINISTRATION OF NIMODIPINE CAPSULES

The FDA is alerting healthcare professionals once again that nimodipine capsules should only be given by mouth or through a feeding tube. Nimodipine capsules should NEVER be given by intravenous administration. The FDA continues to receive reports of intravenous nimodipine use with serious and sometimes fatal consequences. The intravenous use of nimodipine can result in death, cardiac arrest, severe drops in blood pressure, and other heart-related complications.

Nimodipine is intended to be given in a critical care setting to treat neurological complications from subarachnoid hemorrhage and is only available in capsule form. In 2006 the FDA added a Black Box Warning and revised the prescribing information of nimodipine to warn against intravenous use. The prescribing information provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients unable to swallow.

The FDA has identified 31 cases of medication errors since the drug was released in 1996. Of the 31 medication errors, 25 involved erroneous intravenous nimodipine prescribing or administration. Four of the patients who mistakenly received nimodipine intravenously died; five were characterized as having near death events; and one was characterized as having suffered permanent harm as a result of the inadvertent intravenous administration. The following factors have been identified as contributing to this recurring medication error:

- Some patients receiving nimodipine cannot swallow the capsule. They must therefore receive the liquid contained in the capsule through a feeding tube. 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. The liquid contents can then be emptied into a feeding tube. A standard needle will not fit on an oral syringe; therefore, 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 IV instead of by mouth or nasogastric tube.
- Most patients receiving nimodipine are hospitalized in critical care units and are already receiving IV medications.

The Food and Drug Administration believes that ALL healthcare professionals should be made aware that nimodipine is to be administered only by the oral route or via nasogastric tube. All medication errors involving nimodipine capsules should be reported to the FDA via the Med Watch program.^{(1),(2)}

PROAMATINE (MIDODRINE) TO BE REMOVED FROM THE MARKET

The FDA proposed to withdraw approval for the drug midodrine, which is used to treat orthostatic hypotension. The drug was initially approved under the FDA's accelerated approval process which required the drug's manufacturer, Shire, to conduct post marketing studies to demonstrate ProAmatine's clinical benefits. The FDA claims that neither the manufacturer, nor any generic manufacturer has demonstrated the clinical benefit of the drug by showing, for example, that the drug improved the ability to perform life activities. Shire stated that studies were completed but the FDA ruled the studies inconclusive. The FDA also announced that generic forms of the drug will also be banned from sale in the USA unless they pass the agency's normal approval process. Shire announced it will be removing ProAmatine from the market effective September 30, 2010.

ProAmatine continued... →

Drugs That Block Iron Absorption:

- Aluminum Salts
- Calcium Salts
- Magnesium Salts
- Zinc Salts
- Antacids
- Cholestyramine
- Colestipol
- H2 Antagonists
- Proton Pump Inhibitors
- Levothyroxine
- Tetracycline
- Demeclocycline
- Doxycycline
- Minocycline
- Ciprofloxacin
- Moxifloxacin
- Levofloxacin
- Penicillamine

ProAmatine continued...

If you have a patient on midodrine and there is no other suitable substitute, your patient may be able to receive midodrine through an expanded access program. Such use will be determined on a case-by-case basis in patients whose serious or life threatening illness cannot be treated with an alternative medication. ^{(3),(4),(5)}

ADVERSE REACTION UPDATE**Arava – Severe liver injury**

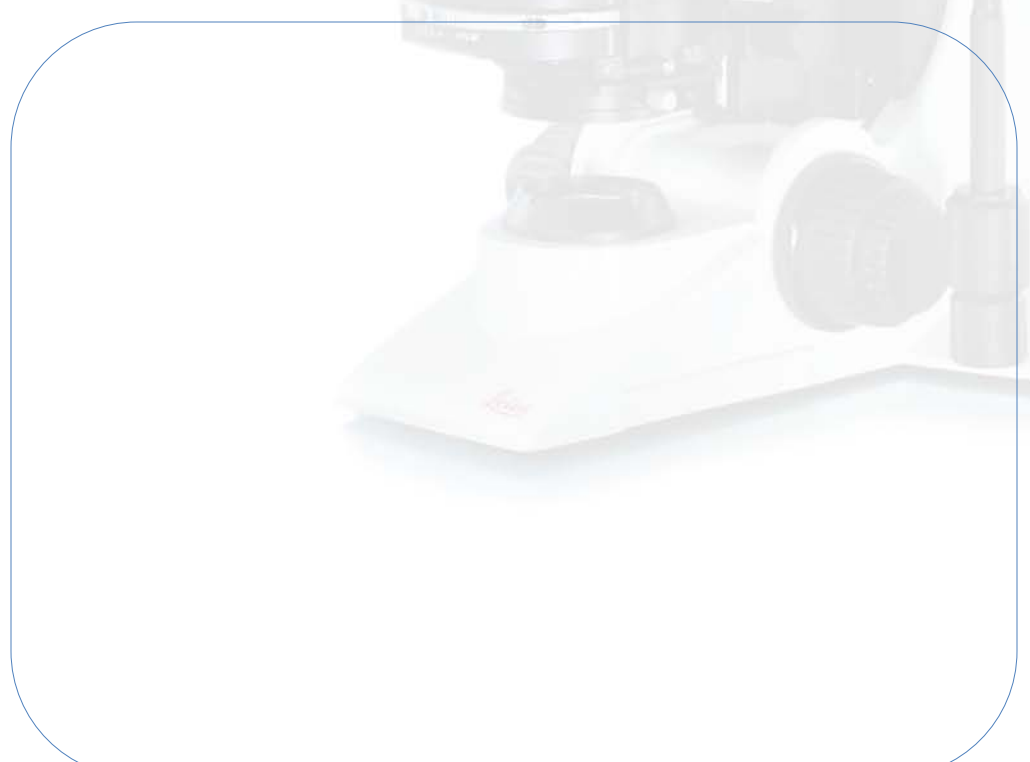
Information on severe liver injury is being added to the prescribing information of Arava (leflunomide), a drug used to treat rheumatoid arthritis. New prescribing information includes the following:

- Patients with pre-existing liver disease should not receive leflunomide
- Patients with elevated liver enzymes should not receive leflunomide
- Liver enzymes should be monitored monthly for three months
- Caution should be used in patients who are taking other drugs that can harm the liver

If the ALT rises to greater than two times the upper limit of normal while the patient is on leflunomide, the drug should be stopped and cholestyramine wash begun to speed removal of leflunomide from the body. Liver function tests should be monitored weekly until the ALT has returned to normal.

Lamictal – Aseptic Meningitis

The FDA is warning healthcare professionals that Lamictal (lamotrigine), a drug used to treat seizures and bipolar disorder, can cause aseptic meningitis. Symptoms of meningitis include headache, fever, stiff neck, nausea, vomiting rash and sensitivity to light. The symptoms occurred 1 to 42 days after patients began taking lamotrigine. Most symptoms resolved when the medication was discontinued but recurred within hours of restarting therapy. The FDA emphasized that a rapid diagnosis of all cases of meningitis is necessary to guide the appropriate treatment. Healthcare providers should now consider Lamictal as a potential causative agent when diagnosing the condition. ^{(6),(7),(8)}

FROM THE DIRECTOR'S DESK**SOURCES**

1. FDA Safety Communication; Post market safety Information for Patients and Providers 8/2/10
2. Pharmacy OneSource Alert 8/3/10
3. FDA news Vol 7, no. 161 8/18/2010
4. Pharmacy OneSource 8/16/2010
5. ASHP News Aug 25, 2010
6. FDA Drug Safety Communication; 7/13/10
7. Pharmacy OneSource Alert: Lamictal; 8/13/10
8. Health-System Pharmacy News; 8/20/10