Due to ISMP Advocacy, VinCRISTine Labeling and Packaging Changed to Prevent Wrong Route Administration

Horsham, Pa. — The Institute for Safe Medication Practices (ISMP) commends the U.S. Food and Drug Administration (FDA) for requesting that Pfizer revise its current prescribing information and product packaging for vinCRISTine to eliminate syringe administration. ISMP has strongly advocated supplying vincristine in minibags since 2001, to avoid the risk of confusion with syringes.

The labeling for vinCRISTine now will state: To reduce the potential for fatal medication errors due to incorrect route of administration, vinCRISTine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated “FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.” In addition, preparation and administration of the drug in a syringe has been totally removed from the package insert.

ISMP has referred to wrong route administration of vinca alkaloids as one of the “most serious of all medication errors,” as death is painful and takes days or weeks, and there is no possible reversal once the mistake is made. More than 140 deaths are known to have occurred from accidental intrathecal injection of vinCRISTine via syringe into the spinal canal. No cases of wrong route errors have been reported with administration of the drug in a minibag.

Dispensing vinCRISTine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first ISMP Targeted Medication Safety Best Practices for Hospitals (www.ismp.org/node/160), which were launched in 2014. ISMP called on the FDA to eliminate syringe administration of vincristine in the March 14, 2019 issue of the ISMP Medication Safety Alert® newsletter (https://www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids).
Other accrediting and professional organizations have helped promote the practice of dispensing vinca alkaloids via minibag, including The Joint Commission (TJC), National Comprehensive Cancer Network (NCCN), Oncology Nursing Society (ONS), American Society of Clinical Oncology (ASCO). NCCN and TJC also requested the FDA change the labeling and packaging for vinCRISTine. Internationally, the World Health Organization (WHO) has promoted dilution of vinca alkaloids in minibags since 2007.

About the Institute for Safe Medication Practices
The Institute for Safe Medication Practices (ISMP) is the only 501c (3) nonprofit organization devoted entirely to preventing medication errors. ISMP is known and respected as the gold standard for medication safety information. For more than 25 years, it also has served as a vital force for progress. ISMP’s advocacy work alone has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging. Among its many initiatives, ISMP runs the only national voluntary practitioner medication error reporting program, publishes newsletters with real-time error information read and trusted throughout the global healthcare community, and offers a wide range of unique educational programs, tools, and guidelines. In 2020, ISMP formally affiliated with ECRI to create one of the largest healthcare quality and safety entities in the world. As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its life-saving work. Learn more at www.ismp.org.