Institute for Safe Medication Practices

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Inaction on Dangerous Packaging Leads ISMP to Call for Replacement of Brethine Ampuls

HUNTINGDON VALLEY, Pa.--The Institute for Safe Medication Practices (ISMP) has issued a ***hazard alert for healthcare providers at hospitals and birthing centers, calling for immediate replacement of BRETHINE (terbutaline) ampuls with the available vials***. The alert was sent after ISMP received yet another report of a medication error resulting from look-alike ampul packaging for Brethine and METHERGINE (methylergonovine), which are frequently used in labor and delivery settings but have opposite effects.

These continuing incidents with Brethine and Methergine expose serious weaknesses in our medication safety and recall systems--long delays often occur in gaining product improvements after significant problems are recognized, and dangerous items remain on the market to cause patient harm long after problems have been corrected. ISMP has published three alerts since 2000 to warn healthcare providers about the potential for Brethine-Methergine mix-ups. These alerts were in response to reports of errors and patient injuries, including suspected cause of fetal demise and cases of premature uterine contractions requiring emergency treatment.

Brethine is used off-label in obstetrics to treat preterm labor and Methergine is used primarily after delivery of the placenta to treat hemorrhage and failure of the uterus to contract. Both continue to be available as 1 mL ampuls within an amber plastic tub covered by a foil label with the product name in tiny print, making them difficult to tell apart. Both ampuls have similar colored "rings" around the ampul necks that can be seen through the plastic, which further adds to their similarity. Brethine should be stored at room temperature while Methergine should be stored under refrigeration.

Brethine manufacturer aaiPharma acquired the product from Novartis in 2001. In a recent communication with ISMP, the company noted that they have taken steps to distinguish the appearance of Brethine to reduce the chance of errors, including repackaging the product in vials instead of ampuls. Brethine ampuls were last shipped in January 2004-- however, they have not been recalled and likely remain in the supply chain. In fact, although the company has indicated they now ship only vials, two of the major drug wholesalers listed only the Brethine ampuls in their computer system when accessed this week (week of October 18, 2004). Generic terbutaline is available from other manufacturers in vials. ISMP is calling for all hospitals and birthing centers to replace Brethine ampul stock with vials to help differentiate it from Methergine.

ISMP also has notified the Food and Drug Administration (FDA) and aaiPharma about the most recent error and asked the company to voluntarily recall the ampul product.

Please contact ISMP media relations at 704-321-3343 or rbrehio@ismp.org to arrange interviews on this issue or for a copy of images that illustrate the similarities in Brethine-Methergine packaging.

About ISMP: The Institute for Safe Medication Practices (ISMP) is a 501c(3) nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents nearly 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. In 2004, the Institute is celebrating the 10th anniversary of is official incorporation as a nonprofit organization. For more information on ISMP, or its medication safety alert newsletters for healthcare professionals and consumers, visit www.ismp.org

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