Bristol-Myers Squibb Pharmaceuticals
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IMPORTANT MEDICINE SAFETY INFORMATION

Risk of Overdose due to Confusion between Lipid- and Non-lipid-based Formulations of Parenteral Amphotericin B, including Fungizone® (Amphotericin B for injection)

Dear Health Care Provider:

Bristol-Myers Squibb would like to inform you of important safety information concerning Fungizone® Intravenous (Amphotericin B for injection).

Parenteral Amphotericin B products differ markedly in relation to dosage and administration, due to differences in product formulations. Based on an analysis of postmarketing safety data, BMS has concluded that there is a potential risk to patients of an overdose of amphotericin B due to confusion between non-lipid and lipid formulations of injectable amphotericin B. Fatal cases of overdose have resulted when Fungizone®, a non-lipid-based injectable formulation of amphotericin B, has been mistakenly administered in lieu of a lipid-based formulation.

Parenteral formulations of amphotericin B are not interchangeable. Particular care must be taken in prescribing the correct brand of Amphotericin B, and prescribers, pharmacists, and nurses need to be fully aware of the brand being prescribed and the associated dosage regimen.

To prevent overdose resulting from confusion among different formulations, BMS has updated the core safety information for Fungizone® (Amphotericin B for injection) as follows:

- **Under no circumstances should a total daily dose of 1.5 mg/kg be exceeded. Amphotericin B overdoses may result in potentially fatal cardiac or cardiorespiratory arrest.**
- **EXERCISE CAUTION to prevent inadvertent** Fungizone® Intravenous **overdose, which may result in potentially fatal cardiac or cardiorespiratory arrest. Verify the product name and dosage pre-administration, especially if dose prescribed exceeds 1.5 mg/kg.**
- **Amphotericin B overdoses may result in potentially fatal cardiac or cardiorespiratory arrest.**

In addition, it is being required that local packages, cartons, and vial labels be modified to carry the following cautionary statements: **STOP! Verify product name and dosage. Total daily dose must not exceed 1.5 mg per kg.**

Bristol-Myers Squibb is in discussion with the Irish Medicines Board regarding revisions to the Fungizone® (Amphotericin B for injection) Product labelling to include the important information mentioned above. This safety issue will continue to be kept under close scrutiny.

Bristol-Myers Squibb encourages healthcare professionals to continue to report suspected adverse reactions, pregnancy, overdose and unexpected benefits for Fungizone® products, via telephone at +44 1895 523740 or via email at medical.information@bms.com.

In addition, if you wish to report a medication error to the Irish Medicines Board, please use the "on-line reporting" section of the IMB website at www.imb.ie or contact the IMB at 01-6764971.

If you have further questions or require additional information, please contact our Medical Information Department at +44 1895 523740.

Yours sincerely,

Siobhán Mitchell

Siobhan Mitchell PhD, Medical Director

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