Bristol-Myers Squibb Pharmaceuticals
South County Business Park. Leopardstown, Dublin 18. Tel. (01) 291 3800 Fax (01) 291 3899

RISK OF ACCIDENTAL OVERDOSE WITH PERFALGAN (INTRAVENOUS PARACETAMOL)

26th March 2012

Dear Healthcare Professional,

Bristol-Myers Squibb in agreement with the Irish Medicines Board (IMB) would like to draw your attention to new risk minimisation advice following continuing reports of accidental overdose with Perfalgan 10 mg/ml (intravenous paracetamol) in neonates and infants.
We also want to draw your attention to the risk of accidental overdose in underweight adults and remind you of the current dose recommendations.

1. Avoiding unintentional over dose in neonates and infants:

- **To avoid dosing errors in neonates and infants and confusion between milligrams (mg) and milliliters (mL), it is recommended to specify the intended volume for administration in mL.**

- **In neonates and infants, very small volumes will be required.**

2. General requirement for weight-based dosing (see table below):

- **The prescribed dose must be based on the patient's weight for patients ≤50kg**

- **Since unintentional overdose can lead to serious liver damage, prescribers are reminded that it is essential to follow both the weight-related dose recommendations and to consider individual patient risk factors for hepatotoxicity including hepatocellular insufficiency, chronic alcoholism, chronic malnutrition (low reserves of hepatic glutathione) and dehydration.**

The following dosing recommendations apply:

For children weighing ≤ 10 kg:

- **The dose in these patients is 7.5 mg/kg**
- **The volume of Perfalgan 10 mg/mL administered should never exceed 7.5 mL per dose in this weight group. Smaller volumes will be required with lower weights.**
- The Perfalgan glass vial/bag should not be hung as an infusion due to the small volume of the medicinal product to be administered in this population.
- A 5 ml or 10 ml syringe should be used to measure the dose as appropriate for the weight of the child and the desired volume.

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- The volume to be administered should be withdrawn from the vial/bag and diluted in a 0.9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Perfalgan into nine volumes diluents) and administered over 15 minutes.

For children, adolescents and adults weighing >33 kg but ≤50 kg:

- **The dose in these patients is 15mg/kg. The maximum daily dose in these patients should not exceed 3g in 24 hours.**
- **The volume of Perfalgan 10mg/mL administered should never exceed 75mL per dose.**

To minimise the risk of medication error with Perfalgan 10 mg/mL, please ensure that this new advice is brought to the attention of all relevant healthcare professionals involved in the prescription, dispensing or administration of this product.

Call for Reporting

Healthcare professionals should report any suspected adverse reaction associated with the use of Perfalgan

Suspected adverse drug reactions should be reported to the Irish Medicines Board (IMB) using the online form at www.imb.ie or using the freepost Yellow Card system. In addition, suspected adverse reactions, pregnancy, overdose and unexpected benefits for Paracetamol (Perfalgan) may also be reported to Bristol-Myers Squibb Pharmaceuticals via telephone at 1 800 749 749 or via e-mail to medical.information@bms.com.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Should you have any questions regarding the use of Perfalgan, please contact Bristol-Myers Squibb Medical Information 1 800 749 749 or via email at medical.information@bms.com.

Yours faithfully,

Siobhan Mitchell

Dr Siobhan Mitchell PhD
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Dosing Table for Perfalgan 10mg/mL

Patient weight	Dose per administration	Volume per administration	Maximum volume per administration based on upper weight limits of group (mL)*	Maximum Daily Dose
≤10 kg	7.5 mg/kg	0.75 mL/kg	7.5mL	30 mg/kg
> 10 kg to ≤33kg	15 mg/kg	1.5mL/kg	49.5mL	60mg/kg not exceeding 2g
> 33 kg to ≤50kg	15 mg/kg	1.5mL/kg	75 mL	60mg/kg not exceeding 3g
>50kg with additional risk factors for hepatotoxicity	1g	100mL	100mL	3g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100mL	100mL	4g

*Patients weighing less require smaller volumes.

The minimum interval between each administration must be at least 4 hours.

The minimum interval between each administration in patients with severe renal insufficiency must be at least 6 hours.

No more than 4 doses to be given in 24 hours.

Ref : NP-IRL-12-08