Bristol-Myers Squibb Pharmaceuticals
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IMPORTANT PHARMACOVIGILANCE INFORMATION

Serious cases of overdose reported in infants and children with PERFALGAN® 10 mg/ml, solution for infusion.

Dear Healthcare Provider,

In agreement with the Irish Medicines Board, Bristol-Myers Squibb would like to draw the attention of healthcare professionals to the risk of **accidental overdose in neonates and infants** during treatment with PERFALGAN 10mg/ml solution for infusion, (50 ml vial) [1].

- **Up to 31st March 2010, 23 international cases of paracetamol overdose had been reported in children aged from 1 day to 1 year who accidentally received a dose 10 times greater than the dose prescribed. One child died.**
- **The origin of this error is the confusion between milligrams (mg) and millilitres (ml) (prescription of x mg, administration of x ml), resulting, in effect, in the administration of a dose 10 times greater than the dose prescribed, the strength of the proprietary medicinal product PERFALGAN being 10 mg/ml.**
- **With this in mind, we should like to:**
  - **remind you that the strength of PERFALGAN solution for infusion is 10 mg paracetamol per 1 ml.**
  - **encourage healthcare professionals to be extremely vigilant when prescribing and administering PERFALGAN 10mg/ml solution for infusion.**

Posology information from the Summary of Product Characteristics (SmPC) is summarised below:

	Term newborn infants*, infants, toddlers and children weighing <10 kg (up to approx 1 year old)	**Children weighing >10 kg and <33 kg**
Dose	7.5 mg/kg per administration **= 0.75 mL solution per kg**	15 mg/kg per administration **= 1.5 mL solution per kg**
Dosing schedule	One IV infusion of 7.5mg/kg **(0.75 mL per kg)** up to four times a day, with a minimum interval of 4 hours between each administration.	One IV infusion of 15mg/kg **(1.5 mL per kg)** up to four times a day with a minimum interval of 4 hours between each administration.
Maximum daily dose	The maximum daily dose must not exceed 30mg/kg.	The maximum daily dose must not exceed 60mg/kg (without exceeding 2g)

* Efficacy and safety data is not available for premature neonates.

[1] This proprietary medicinal product is indicated for the short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever, when administration by intravenous use is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible in children weighing less than 33 kg.

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An example dosing table is also provided below:

Example Dosing Table for PERFALGAN for children weighing less than 33kg

The 50ml vial of PERFALGAN is restricted to term newborn infants, infants, toddlers and children weighing less than 33kg.

Paracetamol (mg/kg)	Weight (kg)	Calculated Dose (mg)	Volume of solution (mL)
	3	22.5	2.25
7.5	5	37.5	3.75
	7	52.5	5.25
	10	75	7.5
	15	**225**	22.5
15	**20**	**300**	30
	30	**450**	45

For method of administration please see the SmPC.

Additional information:
Of these 23 cases reported, 19 cases occurred in the European Union, including 1 case in Ireland.

The death reported concerned a very premature baby who received 7 ml of solution for injection with a strength of 10 mg/ml instead of 0.7 ml, i.e. 70 mg instead of 7 mg. In the other cases, the outcome, in those cases where it was known, was favourable.

In order to ensure the safe use of Perfalgan 10 mg/ml solution for infusion, we would be grateful if you would please circulate this information to healthcare personnel: doctors, pharmacists, hospital department managers and nurses.

Bristol-Myers Squibb encourages healthcare professionals to continue to be vigilant and to report medication errors or suspected adverse reactions with PERFALGAN to the Irish Medicines Board using the online form at www.imb.ie or using the freepost Yellow Card system. In addition, this information may be reported to Bristol-Myers Squibb via telephone at +44 1895 523740 or via email at medical.information@bms.com.

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

Yours sincerely,

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