IMPORTANT DRUG SAFETY INFORMATION

Direct Healthcare Professional Communication on paracetamol, solution for infusion and risk of accidental overdosing of neonates, infants and underweight adults

December 8, 2014

Dear Healthcare Professional,

B. Braun Melsungen AG would like to draw the attention of healthcare professionals to the **risk of accidental overdosing in newborn infants, infants, toddlers and children (≤ 33 kg) and adolescents and underweight adults (≤ 50 kg)** during treatment **with intravenous paracetamol 10 mg/ml solution for infusion**.[1]

- There are concerns regarding the possible confusion between the prescription of Paracetamol 10 mg/ml being issued in mg and then administered in ml. This would result in 10-fold overdose.

- The 50 ml Ecoflac plus is intended for use in toddlers and children weighing more than 10 kg and up to 33 kg. The 100 ml Ecoflac plus must **not** be used for these patient groups.

- **Only** the 10 ml ampoule is intended for use in term newborn infants, infants and toddlers weighing less than or equal to 10 kg. The 50 ml Ecoflac plus and the 100 ml Ecoflac plus must **not** be used for these patient groups.

With this in mind, we would like to remind you that the strength of Paracetamol 10 mg/ml solution for infusion is **10 mg paracetamol per 1 ml solution** and encourage you to be extremely vigilant when prescribing and administering Paracetamol 10 mg/ml solution for infusion to patients weighing ≤ 50 kg. For these patients dosing should be weight-based. Posology information from the Summary of Product Characteristics (SmPC) is summarized below:

10 ml ampoule				
Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)***	Maximum daily dose**
≤ 10 kg*	7.5 mg/kg	0.75 ml/kg	7.5 ml	30 mg/kg

[1] For further information see SmPC

50 ml bottle				
Patient weight	Dose per administration	Volume per administration	Maximum volume of Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)***	Maximum daily dose**
> 10 kg to ≤ 33 kg	15 mg/kg	1.5 ml/kg	49.5 ml	60 mg/kg not exceeding 2 g

100 ml bottle				
Patient weight	Dose (per administration)	Volume per administration	Maximum volume of Paracetamol (10 mg/ml) per administration based on upper weight limits of group (ml)***	Maximum daily dose**
> 33 kg to ≤ 50 kg	15 mg/kg	1.5 ml/kg	75 ml	60 mg/kg not exceeding 3 g
> 50 kg with additional risk factors for hepatotoxicity	1 g	100 ml	100 ml	3 g
> 50 kg and no additional risk factors for hepatotoxicity	1 g	100 ml	100 ml	4 g

*Preterm newborn infants:
No safety and efficacy data are available for premature newborn infants.

** Maximum daily dose: The maximum daily dose as presented in the table above is for patients that are not receiving other paracetamol containing products and should be adjusted taking such products into account.

***Patients weighing less will 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.

[1] For further information see SmPC

For method of administration please see SmPC.

The following additional measures were taken by the company:

- a poster with detailed dosing instructions is available
- a dosage calculator is available

Additional information:

The information in this letter has been agreed with the Health Products Regulatory Authority.

This Direct Healthcare Professional Communication along with the enclosed poster and dosage calculator supercede any previous versions of these documents which may have been provided to you, which should now be discarded.

B. Braun Melsungen AG encourages healthcare professionals to continue to be vigilant and to report suspected adverse reactions with Paracetamol 10 mg/ml to the Health Products Regulatory Authority via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. In addition, this information may be reported to B. Braun Melsungen AG via telephone at (01)7091800 or via email at info.ie@bbraun.com.

If you have further questions or require additional information, please contact our Regulatory Affairs Department at (01)7091800.

Yours sincerely,

Bill Proctor
Business Unit Manager (IV Therapeutics)
B. Braun Medical Ltd.

Roberta Egan
Regulatory Affairs Manager
B. Braun Medical Ltd.

[1] For further information see SmPC