DIPARTIMENT TAS-SAĦĦA DEPARTMENT OF HEALTH
MALTA

L-Uffiċċju tal-Uffiċjal Mediku Ewlieni *Office of the Chief Medical Officer*

DH CIRCULAR No.146/2014

DH 1696/2014

17 April 2014

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Risk Management Plan of Perfalgan® (paracetamol 10mg/mL solution for infusion)

Please find annexed the updated Risk Management Material related to the Risk Management Plan for Perfalgan® brand of paracetamol injections as per agreement between the manufacturing company Bristol Myers Squibb and the Medicines Authority.

For your attention please.

Dr. Neville Calleja
Acting Chief Medical Officer

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Annex 1

AM Mangion Ltd

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Website: www.ammangion.com.mt
Bankers HSBC Bank Malta PLC - St. Julians
Registration: C4112
VAT Reg. No.: MT12619204

3 March, 2014

Dear Healthcare Professional,

Bristol-Myers Squibb would like to inform you that their product Perfalgan (paracetamol, 10 mg/ml solution for infusion) is linked to a Risk Management Plan to reduce risk of dosing errors during administration. For this purpose, thorough their official local representatives A.M. Mangion Ltd., BMS is providing you with Risk Management Materials as approved by the Medicines Authority (Malta) to minimize the risk of dosing errors.

Please note that any medical queries/ adverse drug reactions / product quality complaints related to Perfalgan may be addressed as indicated on the materials to A.M. Mangion Ltd. Pharmacovigilance contact points. However, A.M. Mangion Ltd. is not the current supplier of Perfalgan and will not manage any marketing/supply queries for the time being.

Kind regards,

Roger Aquilina
BMS representative

Perfalgan® 10 mg/mL

paracetamol 500 mg — paracetamol 1 g

Solution for infusion

Short-term treatment of moderate pain, especially following surgery and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible[1]

CAUTION IS REQUIRED WHEN ADMINISTERING PERFALGAN® 10 mg/mL TO AVOID CONFUSION BETWEEN MILLIGRAM (mg) and MILLILITER (mL) WHICH COULD RESULT IN ACCIDENTAL OVERDOSE OR DEATH

Take care to ensure the proper dose is communicated and dispensed. When writing prescriptions, include both the total dose in mg and the total volume in mL. Take care to ensure the dose is measured and administered accurately.

➢ Administration protocol in term neonates, infants and children weighing less than 10 kg [1]

(Posology expressed in mg/kg paracetamol)

1 mL = 10 mg

Patient weight	Single dose	Maximum daily dose**
≤10 kg *	7.5 mg/kg i.e. 0.75 mL/kg	• Up to four times a day • The minimum interval between each administration must be 4 hours • The maximum daily dose must not exceed 30 mg/kg

* Pre-term newborn infants: No safety and efficacy data are available for pre-term 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 accordingly taking such products into account.

The volume of Perfalgan 10 mg/mL administered should never exceed 7.5mL per dose in patients weighing ≤ 10 kg

Child's weight ≤ 10kg	Volume to be administered	Correspondence in mg
1 kg	0.75 mL	7.5 mg
1.5 kg	1.1 mL	11 mg
2 kg	1.5 mL	15 mg
2.5 kg	1.8 mL	18 mg
3 kg	2.2 mL	22 mg
3.5 kg	2.6 mL	26 mg
4 kg	3.0 mL	30 mg
4.5 kg	3.3 mL	33 mg
5 kg	3.7 mL	37 mg
5.5 kg	4.1 mL	41 mg
6 kg	4.5 mL	45 mg
6.5 kg	4.8 mL	48 mg
7 kg	5.2 mL	52 mg
7.5 kg	5.6 mL	56 mg
8 kg	6.0 mL	60 mg
8.5 kg	6.3 mL	63 mg
9 kg	6.7 mL	67 mg
9.5 kg	7.1 mL	71 mg
10 kg	7.5 mL	75 mg

For patients weighing ≤ 10 kg the following recommendations apply:

- **Administer the dose over 15 minutes**
- **Do not hang the vial as an infusion**
- **Use a 5 or 10 mL syringe to measure the dose as appropriate for the weight of the child and the desired volume**
- **The volume to be administered should be withdrawn from the vial and diluted in a 0,9% sodium chloride solution or 5% glucose solution up to one tenth (one volume Perfalgan into nine volumes diluents)**

Suspected adverse reactions and medication errors associated with the use of PERFALGAN should be reported to:

Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gzira GZR 1368, or at: http://www.medicinesauthority.gov.mt/pub/adr.doc

Healthcare professionals and patients may also report any adverse events and medication errors suspected to be associated with the use of Perfalgan to AM Mangion Ltd. by phone on 23976333, by fax on 23976123 or e-mail at pv@ammangion.com.mt.

1) Summary of Product Characteristics PERFALGAN® and PERFALGAN® infants and children

Bristol-Myers Squibb Pharma

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DOSING TOOL

Short-term treatment of moderate pain, especially following surgery and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible. [1]

Administration protocol. Dosing table for Perfalgan® 10 mg/mL [1]

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	7.5 mL	30 mg/kg
> 10 kg to ≤ 33 kg	15 mg/kg	1.5 mL/kg	49.5 mL	60 mg/kg not exceeding 2 g
> 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

* 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.

[1] Summary of Product Characteristics of Perfalgan® 10 mg/mL, solution for infusion

10 mg = 1 mL

Patient weight	Volume of Perfalgan®	Quantity of Perfalgan®
kg	mL	mg

SOLUTION FOR INFUSION

Perfalgan® paracetamol 10 mg/mL

Perfalgan® paracetamol 10 mg/mL

SOLUTION FOR INFUSION

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

Suspected adverse reactions and medication errors associated with the use of PERFALGAN should be reported to:

Medicines Authority Post-licensing Directorate, 203 Level 3, Rue D'Argens, Gzira GZR 1368, or at: http://www.medicinesauthority.gov.mt/pub/adr.doc

Healthcare professionals and patients may also report any adverse events and medication errors suspected to be associated with the use of Perfalgan to AM Mangion Ltd by phone on 23976333, by fax on 23976123 or e-mail at: pv@ammangion.com.mt

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For more information, refer to the Summary of Product Characteristics of Perfalgan® 10 mg/mL, solution for infusion.

Bristol-Myers Squibb

Perfalgan®

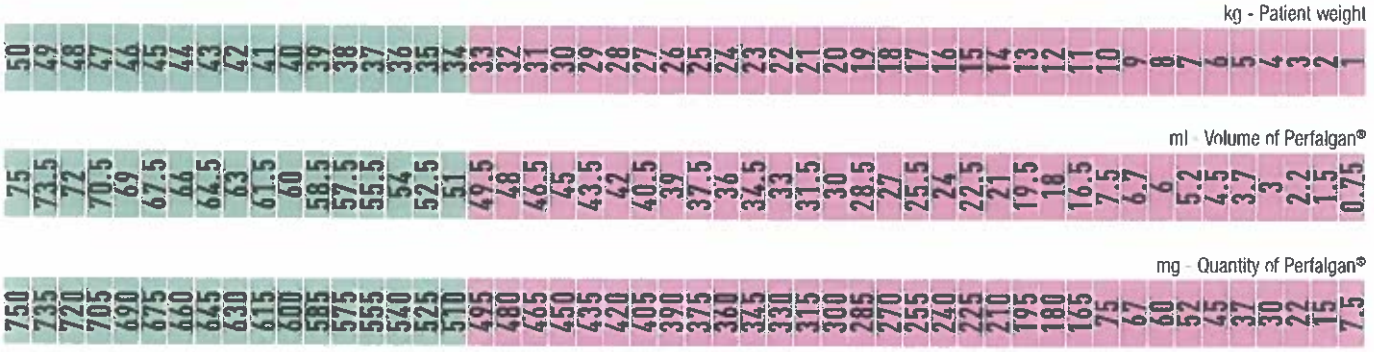
paracetamol 10 mg/mL

SOLUTION FOR INFUSION

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.



Short-term treatment of moderate pain, especially following surgery and for the short-term treatment of fever, when administration by intravenous route is clinically justified by an urgent need to treat pain or hyperthermia and/or when other routes of administration are not possible. [1]

[1] Summary of Product Characteristics of Perfalgan® 10 mg/mL, solution for infusion

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