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Fresenius Kabi New Zealand Limited

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Shortage of PARACETAMOL KABI 1000mg/100mL solution for injection vial and Temporary supply of Malaysian Labelled Product

Dear Healthcare Professional,

Fresenius Kabi New Zealand Limited is currently facing a supply shortage of PARACETAMOL KABI 1000mg/100mL solution for injection packaged in the New Zealand approved labelling. To address this issue, Fresenius Kabi has been able to arrange supply of the Malaysian labelled product **Paracetamol Kabi 10mg/mL solution for infusion vials** on a temporary basis. The Malaysian product does not comply with New Zealand labelling requirements however the formula, concentration, volume, dosage form and manufacturer are identical to the current product.

The Malaysian label will look different to the current label, please be aware of the difference in the presentation of strength and storage recommendations as shown below:

	Current product PARACETAMOL KABI 1000mg/100mL solution for injection vial	Malaysian product PARACETAMOL KABI 10mg/mL solution for infusion vials	
Strength	1000mg/100mL 10mg/mL		
Storage	Store below 25°C. Do not refrigerate or freeze.	Store below 30°C. Do not refrigerate or freeze.	
Label	PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN 1000mg / 100mL Paracetamol Kabi Paracetamol Nobing / 100ml Solution for Injection For Intravenous Infusion Only. Each 100mL vial contains paracetamol 1g Also contains excipients: water for injections 96.6g, mannitol 3.7g, cysteline flydrochoide 10 mg and nitrogen gs. Use in one patient on one occasion only. Contains no antimicrobial preservative. Discard any residue. Directions for use. Please refer to the enclosed package insert. Store below 25°C. Do not refrigerate, do not freeze. **TERSENIUS** KABI Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way, Mount Kuring-gai NSW 2080 Manufactured by: Fresenius Kabi Fredberg, Germany Manufactured by: Fresenius Kabi Graz, Austria **Tessenius Kabi Graz, Austria	Paracetamol Kabi 10 mg/ml Solution for infusion Paracetamol Kabi	

The supply of the temporary Malaysian labelled product will only affect one batch as stated in the table below:

Product	Batch
Paracetamol Kabi 10mg/mL solution for infusion vials	14TC21

Healthcare Professionals are advised to disregard the package insert that is supplied with the Malaysian labelled product and refer to the New Zealand Datasheet for Indications and Method of Administration available at https://www.medsafe.govt.nz/Medicines/infoSearch.asp.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Healthcare professionals and patients are encouraged to report any adverse events experienced with the Malaysian-labelled product to the Centre for Adverse Reactions Monitoring (CARM)/Medsafe at: https://pophealth.my.site.com/carmreportnz/s/. Alternatively, please report adverse events to Fresenius Kabi New Zealand Limited on 0800 144 892 or by email at medical.information@fresenius-kabi.com.

Please forward this information to relevant staff members in your organisation.

Consent has been obtained from Medsafe regarding this temporary arrangement. Fresenius Kabi is committed to bringing you stock with New Zealand compliant labelling as soon as possible.

Should you require any further information, please do not hesitate to contact Fresenius Kabi New Zealand Limited on 0800 144 892 or by email at medical.information@fresenius-kabi.com.

Yours sincerely,

Munupas

Ram Kamath

Director Regulatory and Medical Affairs, Quality Management

Fresenius Kabi New Zealand Limited