PLEASE DISTRIBUTE TO OTHER HEALTHCARE PROFESSIONALS IN YOUR FACILITY

Pfizer Australia Pty Ltd
ABN: 50 008 422 348
38 - 42 Wharf Road
West Ryde NSW 2114
Australia

21st June 2018

Dear Healthcare Professional,

URGENT MEDICINE RECALL

TGA Reference Number: RC-2018-RN-00641-1
DBL™ METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bag
AUST R 129476

Presentation	Product Code	Batch/ Expiry
DBL METRONIDAZOLE INTRAVENOUS INFUSION 500mg/100 mL solution for injection bags	**M8241D001 (10 pack)**	**All batches within expiry**

Pfizer Australia Pty Ltd advises that, after consultation with the Therapeutic Goods Administration (TGA), **all batches within expiry of METRONIDAZOLE INTRAVENOUS INFUSION 500mg/100 mL solution for injection bags, AUST R 129475** are being recalled. We are contacting you as the potentially affected product may have been supplied to your organisation.

This medicine recall is an escalation of the Hospital Level Product Defect Alert issued on 4th June 2018 and as such, those instructions are superseded by this Recall.

FUTURE SUPPLY

Pfizer Australia Pty Ltd is working with the TGA to arrange supply of suitable alternatives on a temporary basis. A separate communication will be provided once details are confirmed.

ISSUE

A number of customer reports recently received indicate that DBL METRONIDAZOLE INTRAVENOUS INFUSION had visible black particles reported as mould between the infusion bag (primary packaging) and plastic overwrap (secondary packaging).

The unlikely growth of mould in between the sterilised primary bag and non-sterile secondary overwrap bag is considered to occur as a result of the primary bag slowly leaking and the collection of the leaked solution over an extended period of time in a non-sterile secondary bag.

The potential risk to a patient arising from the unlikely exposure to impacted metronidazole product is considered to be medium to high, given the theoretical possibility of a systemic infection, particularly for immunocompromised patients.

The incidence of this type of complaint is considered low.

ACTION

Please inspect your stock and quarantine all batches within expiry of DBL METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bags.

If you have stock, then:

- Please return this affected stock to your wholesaler or point of sale to issue you with a credit.

This action must be completed by 3rd August 2018.

When affected batches of DBL METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bags are received, the wholesaler will process your credit.

If any of the recalled stock may have been transferred from your hospital to another, please immediately let that hospital know of the urgent recall by forwarding a copy of this letter. Otherwise, please contact your wholesaler and they will contact them directly.

Please ensure all relevant staff members are informed of this Urgent Product Recall, including locums and relevant clinicians.

Please display this letter in prominent positions in your hospital that are easily accessible to all staff who administer DBL METRONIDAZOLE INTRAVENOUS INFUSION bags.

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines.

Please direct any adverse event reports or medical enquiries regarding DBL METRONIDAZOLE INTRAVENOUS INFUSION metronidazole 500mg/100mL solution for injection bags to Pfizer Medical Information on 1800 675 229.

Adverse events may also be reported direct to the TGA
(http://www.tga.gov.au/reporting-problems)

Thank you for your assistance in helping us to manage this Urgent Product Recall.

Pfizer Australia sincerely regrets any inconvenience caused to you or your organization as a result of this recall.

Yours sincerely,

Wayne Lee | Associate Medical Director | Pfizer Essential Health