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Department of Health
Therapeutic Goods Administration

Medicines Safety Update

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In this issue

Intravenous solution bags are designed for single use only

Health professionals are reminded that intravenous (IV) solution bags are designed for single use only and there are no circumstances where they should be reconnected (re-spiked) after first use.

Re-spiking is the process of inserting a giving set into an already used or previously spiked IV bag.

IV fluids are administered via a plastic IV solution bag which collapses on itself as it empties.

When a bag is disconnected by removing the giving set spike, air can enter the bag. If it is then reconnected to an IV line, air can potentially enter the patient's vein and cause an air embolism. For this reason, partially used IV bags must never be re-spiked.

All IV bags are designed for single use only – for use in one patient and on one occasion only. All registered large volume injections, including IV bags, are required to have this warning (or words to the same effect) clearly displayed on the labelling.

The TGA has received one report of air embolism associated with an IV bag being re-spiked, which resulted in the death of a child. While this is the only report the TGA has received, the risks to patients are extremely serious and it is possible this issue has been under-reported.

In addition to the potential risk of introducing an air embolus, re-spiking can also result in contamination of the fluid, which may lead to infection and bacteraemia.

Additional safety considerations

In addition to never re-spiking IV bags, health professionals are reminded of the risks of pressurising IV bags to increase flow rates in emergency situations.

If residual air in the bag or infusion set is not removed first, pressurised administration can force the air into the patient's vein and result in an air embolism.

Always ensure that the administration set/line is correctly primed and void of all air before connecting to the patient.

As with any therapeutic product, IV bags should always be used in strict accordance with the instructions for using the products.

'Use in one patient on one occasion only.'

Medicine shortages information

The Medicine Shortages Information Initiative provides information about a temporary or permanent disruption to the supply of a prescription medicine. Health professionals and consumers are invited to subscribe to the Medicine Shortages email list to receive an alert when there is new or updated medicine shortage information reported to the TGA.

Medicines Safety Update is the medicines safety bulletin of the Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

Improved labelling for allergens

Health professionals are advised that the TGA is implementing new rules for medicine labels to include improved information about potential allergens.

While certain allergens, such as peanuts and gluten, were already required on medicine labels, the new rules include a longer list of substances that must be declared. The additional substances include crustacea, fish, eggs, soya, milk and tree nuts.

Additionally, for the first time prescription medicines are also required to declare potential allergens on their labels, or include a statement directing consumers to the Consumer Medicine Information leaflet for further information.

In some circumstances, allergens do not need to be declared on the medicine label. For example, some substances may only cause a reaction if they are administered orally and therefore don't have to be declared if the medicine is only for topical use, and some substances are only declared if there is a certain amount in the product. Further details can be found in Schedule 1 to Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines and Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines.

A full list of the substances that need to be declared, as well as other relevant information, is available on the TGA website.

Sponsors will have four years to implement these changes and fully comply with the new rules.

During this transition period, it may be difficult for consumers to know whether their medicine's label includes the more comprehensive list of potential allergens. For this reason, the TGA has been undertaking targeted communications to consumers regarding the changes and specifically advising them to 'keep asking your doctor, pharmacist or other health professional about food allergen content in medications'.

If you are treating patients with known allergies, consider discussing these labelling changes with them (graphics showing where to find allergen information on their medicine's label is now available on the TGA website). In particular, it may be important to ensure patients with less common allergies understand that some potential allergens will still not be covered in the new labelling rules. Additionally, during the transition period, you may need to contact the sponsor of a specific medicine to confirm if it contains any potential allergens (these contact details are provided on the medicine label).

MedSearch app offers quick and easy access to PIs and CMIs

Health professionals and their patients can now gain easy access to up-to-date Product Information and Consumer Medicine Information for registered prescription medicines using the TGA's new MedSearch app.

MedSearch is now available for free download from Google Play and the Apple App Store.

Having Product Information (PI) and Consumer Medicine Information (CMI) available through a mobile application provides users valuable information on the safe and effective use of medicine anywhere, any time. Each time a PI or CMI is downloaded, MedSearch will automatically access the most recent version, providing the most current information possible.

Users can save their 'favourite' PIs and CMIs using the star icon. Favourites can then be quickly and easily accessed through the main menu. The app also makes it easy for users to share links to documents with other people via other applications, such as email.

The MedSearch app will undergo periodic updates to uphold and improve functionality.

Further information about the app, including answers to commonly asked questions and a downloadable poster designed for pharmacies, is available on the TGA website.

Health professionals are encouraged to download MedSearch and use it and to also consider recommending it to patients, especially when prescribing new medicines.

What to report? You don't need to be certain, just suspicious!

The TGA encourages the reporting of all **suspected** adverse reactions to medicines, including vaccines, over-the-counter medicines, and herbal, traditional or alternative remedies. We particularly request reports of:

- all suspected reactions to new medicines
- all suspected medicines interactions
- suspected reactions causing death, admission to hospital or prolongation of hospitalisation, increased investigations or treatment, or birth defects.

Reports may be submitted:

- **using the 'blue card'** available from the TGA website
- **online** at www.tga.gov.au
- **by fax** to 02 6232 8392
- **by email** to ADR.Reports@tga.gov.au

For more information about reporting, visit www.tga.gov.au or contact the TGA's Pharmacovigilance and Special Access Branch on 1800 044 114.

DISCLAIMER

Medicines Safety Update is aimed at health professionals. It is intended to provide practical information to health professionals on medicine safety, including emerging safety issues. The information in Medicines Safety Update is necessarily general and is not intended to be a substitute for a health professional's judgment in each case, taking into account the individual circumstances of their patients. Reasonable care has been taken to ensure that the information is accurate and complete at the time of publication. The Australian Government gives no warranty that the information in this document is accurate or complete, and shall not be liable for any loss whatsoever due to negligence or otherwise arising from the use of or reliance on this document.

For the latest safety information from the TGA, subscribe to the TGA Safety Information email list via the TGA website

For correspondence or further information about Medicines Safety Update, contact the TGA's Pharmacovigilance and Special Access Branch at ADR.Reports@tga.gov.au or 1800 044 114

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