October 2020

Propofol 10 mg/ml (1%) Emulsion for Injection/Infusion – Batches with deactivated data in European Medicines Verification System (EMVS)

Dear Healthcare Professional,

MA#	Batch No.	Description	Expiry date	Quantity
PL 00116/0674	A0D0428	Propofol 10mg/ml Emulsion for Injection/infusion	30-Apr-22	8,755
	A0D0524		31-May-22	8,790
	A0D0528		31-May-22	8,760

Summary

- Packs of propofol from these batches will return a status of 'destroyed' if scanned. However, the units in these batches are acceptable for use and batches can be supplied
- Manually verify batches against any potential falsification by checking that the anti-tamper device is in place. This takes the form of a transparent security sticker on the carton.

Background to the safety concern

Propofol 10 mg/ml is a short-acting intravenous general anaesthetic agent. Propofol is a serialized product which falls under the EU Falsified Medicines Directive and requires verification of product labelling by scanning prior to use.

During shipment of batches from our manufacturing plant a number of packs of propofol became damaged. This required them to be decommissioned from the European Medicines Verification System (EMVS), however a coincidental software bug resulted in the intervention of our software vendor. During the data correction using a manual "Product Pack State Update' by the vendor, all packs were selected resulting in the complete batches being registered as destroyed. Unfortunately, it is not possible to repost the data to EMVS because once it is destroyed, it cannot be re-activated.

As a result of this error, if packs of propofol from these batches are scanned, they will return a status of 'destroyed'. However, the units in these batches are acceptable for use and as supplies of propofol are limited due to increased usage during the Covid-19 pandemic, the MHRA has agreed that these batches can be supplied.

Prior to use, it is recommended that each pack from the batches listed below are manually verified against any potential falsification by checking that the anti-tamper device is in place. This takes the form of a transparent security sticker on the carton. If the bar code is scanned a status of 'destroyed' will be received, but packs may still be used.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

Baxter Healthcare Ltd
Caxton Way / Thetford / Norfolk / IP24 3SE / Great Britain
T 01842 767000 **F** 01842 767099
Registered Office: Caxton Way / Thetford / Norfolk / IP24 3SE Registered in England No. 461365

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.
Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on 01604 704603, or by email to UK_SHS_QA_Complaints@baxter.com.

If you have any medically-related questions about the information contained in this letter, or the use of the imported product, please contact Baxter Medical Information on 01635 206345 or email medinfo_uki@baxter.com.

Yours faithfully,
Baxter Healthcare Ltd.

Donna Vinnels
Head of Regulatory Affairs, UK Ireland & Malta

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