Date: 29 March 2021

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

CHOLEDIAM, kit for the preparation of technetium [^{99m}Tc] mebrofenin injection (Mebrofenin):
Interim Supply of French Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: MEDIAM is currently experiencing supply disruption with CHOLEDIAM, kit for the preparation of technetium [^{99m}Tc] mebrofenin injection (Mebrofenin) in the UK.

To ensure continuity in supply during the current Covid-19 situation, MEDIAM has obtained approval from the MHRA to supply French product, which is expected to be on the UK market from March to 22 May 2021

Batch number	Batch size	Expiry Date	Origin
F00720001	2500 vials	22/05/2021	France

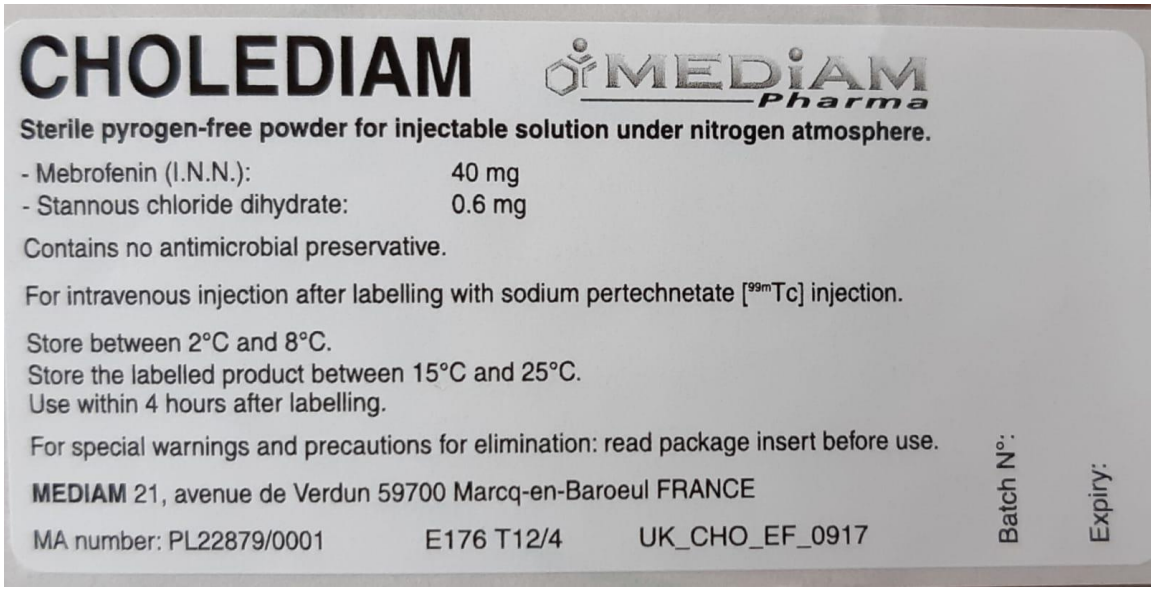
Please note the following:

- This product is considered licensed in the UK (PL/22879/0001).
- The product from France has the same formulation as the UK product
- The product from France is manufactured according to the same manufacturing process as the UK product.
- There are differences between the French and UK product information: the language is different
- Please refer to the UK approved PIL supplied with the French packs. Discard the French leaflet in the pack.
- For additional copies of the leaflet, please contact the company contact point (see below).
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

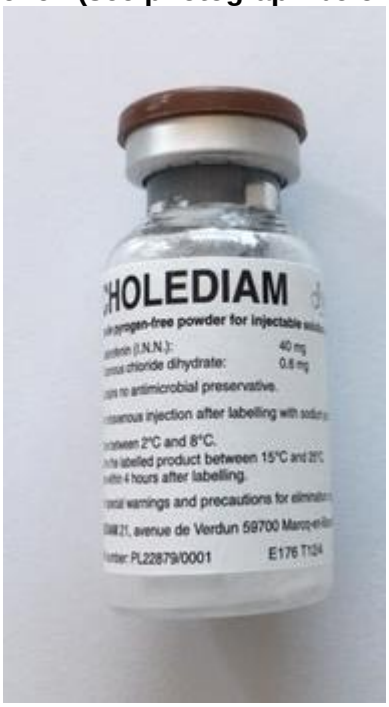
MEDIAM - 21, avenue de Verdun
F-59700 Marcq-en-Baroeul - FRANCE
Tel: +33 3 20 49 72 58
contact@mediam-pharma.com

The carton will be over-labelled with the following label:



In order to not break the anti-tampering device, the vials will not be over-labelled and the information on the immediate label will be in French (see photograph below).:

French CHOLEDIAM vial



Original UK CHOLEDIAM vial

Please refer to the UK approved PIL supplied outside the box of CHOLEDIAM for the translation of this information in English.

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

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IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or wish more information about CHOLEDIAM, please contact MEDIAM Medical Information via email to contact@mediam-pharma.com or telephone +33 3 20 49 72 58.

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