



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy Level

Date: 08 November 2021

EL (21)A/27

Our Ref: MDR 113-12/20

Dear Healthcare Professional,

Vygoris Limited

Mitocin (mitomycin) 20mg powder for solution for injection/infusion or intravesical use

PL 47587/0002

Batch Number	Expiry Date	Pack Size	First Distributed
0-20071AB	31/07/2023	Single Vial	23/10/2020
0-20081AB	31/08/2023	Single Vial	23/10/2020
0-20102AB	31/10/2023	Single Vial	08/01/2021
0-20112AA	30/11/2023	Single Vial	16/02/2021
0-20042AA	30/04/2023	Single Vial	01/07/2020
0-20013AD	31/01/2023	Single Vial	21/04/2021

Active Pharmaceutical Ingredients: mitomycin

Brief description of the problem

Vygoris Limited has informed the MHRA that some vials of Mitocin 20mg powder for solution for injection/infusion or intravesical use may contain subvisible particles above the current specifications after reconstitution ($>10\mu\text{m}$: NMT 6000/vial), initially identified during stability studies. Vygoris Limited has confirmed that a single-use filtration device called the Millex® HV (0.45 μm /PVDF) - Syringe Filter will be included in each delivery of the product.

This product is not being recalled and Vygoris Limited have confirmed that all packs currently in stock (at wholesalers) will be distributed onwards with a filter, and this stock, with filters will be available w/c 08 November 2021. Additionally, filters will be available with all new batches manufactured. If the pack arrives without a filter, please contact Vygoris Limited or Mawdsleys as detailed below.

Advice for healthcare professionals

- Check the existing stock within your possession and identify if any of the Mitocin 20mg powder for solution for injection/infusion or intravesical batches listed above are impacted by this issue. Please note that in addition to your pharmacy, this includes clinics, wards and any other relevant locations.
- Ensure that prior to treatment and where possible, filters are used. The filter remains available for dispatch from Vygoris Limited. Please contact Mawdsleys if you require filters directly.



MPW – Quest 90
Quest Park, Wheatley Hall Road
Doncaster
DN2 4LT
michelle.biggs@mawdsleys.co.uk
Tel: +44 (0) 161 741 3365

Further Information

For medical information queries, please contact:

Lucy Owen,
ProductLifeGroup
+44 (0) 1223 402660
lowen@productlife-group.com

For more information or stock control queries, please contact:

Hussain Tahan
Vygoris Ltd
020 3865 1682
qualitylimited@vygoris.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574