



Department of  
**Health**

An Roinn Sláinte

Máinnystrie O Poustie

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**For Action:** Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO  
Heads of Pharmacy and Medicines Management of HSC Trusts  
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer  
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Our Ref: PHC/29/2021  
Date: 8 November 2021

## MEDICINES NOTIFICATION

### CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy Level**

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  $\mu\text{m}$ /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](mailto: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](mailto:lowen@productlife-group.com)

For more information or stock control queries, please contact:


Hussain Tahan  
Vygoris Ltd  
020 3865 1682  
[qualitylimited@vygoris.com](mailto:qualitylimited@vygoris.com)

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



Mrs Cathy Harrison  
Chief Pharmaceutical Officer