Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 16 May 2023 EL (23)A/17 Our Ref: MDR 070-04/23.

Dear Healthcare Professional,

Novartis Pharmaceuticals

Simulect 10mg powder and solvent for Solution for injection or infusion **PLGB 00101/1143**

SNOMED Code 5007811000001106

Batch Number	Expiry Date	Pack Size	First Distributed
SHVF3	30/09/2025	1 x 10mg glass vial 1 x WFI ampoule	28/02/2023

Simulect 20mg powder and solvent for Solution for injection or infusion **PLGB 00101/1144**

SNOMED Code 4773411000001103

Batch Number	Expiry Date	Pack Size	First Distributed
SHWU5	30/09/2025	1 x 20mg glass vial 1 x WFI ampoule	21/03/2023
SHEW5	31/07/2025	1 x 20mg glass vial 1 x WFI ampoule	08/12/2022
SHFV1	31/07/2025	1 x 20mg glass vial 1 x WFI ampoule	22/12/2022

Active Pharmaceutical Ingredient: Basiliximab

Brief description of the problem
Novartis Pharmaceuticals has informed the MHRA that the solvent (water for injections in ampoules) co-packed with the impacted batches of Simulect powder for injection, may contain glass fragments approximately 20 – 800 µm in size. Therefore, the included solvent should not be used, but replaced with an alternative water for injection. The quality of the Simulect vials themselves is not affected and due to supply considerations, the impacted batches are not being recalled.

The solvent (water for injection in ampoules) shown below in Figure 1 should be discarded as per the advice for healthcare professionals below.

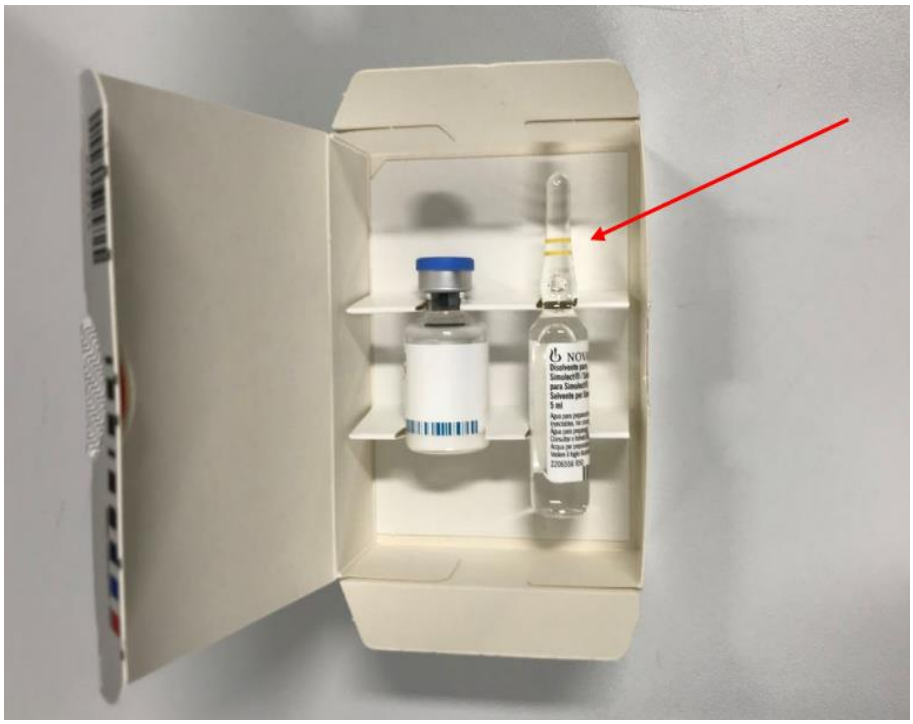

Figure 1 - Solvent (water for injection) ampoule

Advice for healthcare professionals

Novartis Pharmaceuticals has directly notified customers and previously shared considerations for the impacted batches mentioned in this notification. The following actions should be taken:

- discard the solvent (water for injections) co-packed with batches of Simulect at the time of opening the pack. The entire ampoule should be discarded carefully and as per local procedures.
- source alternative water for injection for use as the solvent with Simulect powder. These options should be readily available across secondary care settings.
- the water for injection should comply with European Pharmacopoeia requirements for water for injection, which will be the case if using a licensed product.
- healthcare professionals should continue to safely administer Simulect from the impacted batches using an alternative source of water for injections, following reconstitution as per the Summary of Product Characteristics (SmPC):
    - Simulect 10mg powder: https://www.medicines.org.uk/emc/product/2230/smpc
    - Simulect 20mg powder: https://www.medicines.org.uk/emc/product/7834/smpc
- forward a copy of this notification to all facilities or departments within your hospital or clinic that may use this product.

Additionally healthcare professionals should complete the enclosed Customer Reply Form (Appendix 1) and return it to Novartis by emailing it into the mailbox - commercial.team@novartis.com, within 3 working days.

Advice for patients
No further action is required by patients. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Any suspected adverse reactions should be reported via the MHRA Yellow Card scheme.

Further Information
For more information, medical or supply enquiries, please contact 01276 698370, or email medinfo.uk@novartis.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

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Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk

Appendix 1: Novartis Pharmaceuticals: Customer Reply Form

CUSTOMER REPLY FORM

09 May 2023

Product	Batch Number	Associated lot number of WFI ampoules	Quantity (received number of Simulect packs.)	Expiration Date	Number of discarded ampoules
Simulect 20 mg vial	SHWU5	**M2139**		30/09/2025	
Simulect 20 mg vial	SHEW5	**M0797**		31/07/2025	
Simulect 20 mg vial	SHFV1	**M0797**		31/07/2025	
Simulect 10 mg vial	SHVF3	**M2139**		30/09/2025	

Please complete and sign this form within 1 working day. Email a scanned copy to **commercial.team@novartis.com** as a confirmation that you have received this notification. A cover sheet is not required.

Please note that ***NOVARTIS CANNOT PROCESS UNSIGNED FORMS.***

Completed By: _____ **Title:** _____

Print Name

Address and Phone Number: _____

Signature:_____ **Date:**_____/_____/_____

Your signature above indicates your understanding of the contents of the attached letter and that you performed the actions outlined and disseminated this information, if applicable.