URGENT PRODUCT ALERT

Do not use Water for Injection (WFI) ampoules co-packed with Simulect 20mg Lyophilized Product in Vials product

Basiliximab 20mg

Medsafe Ref 30962

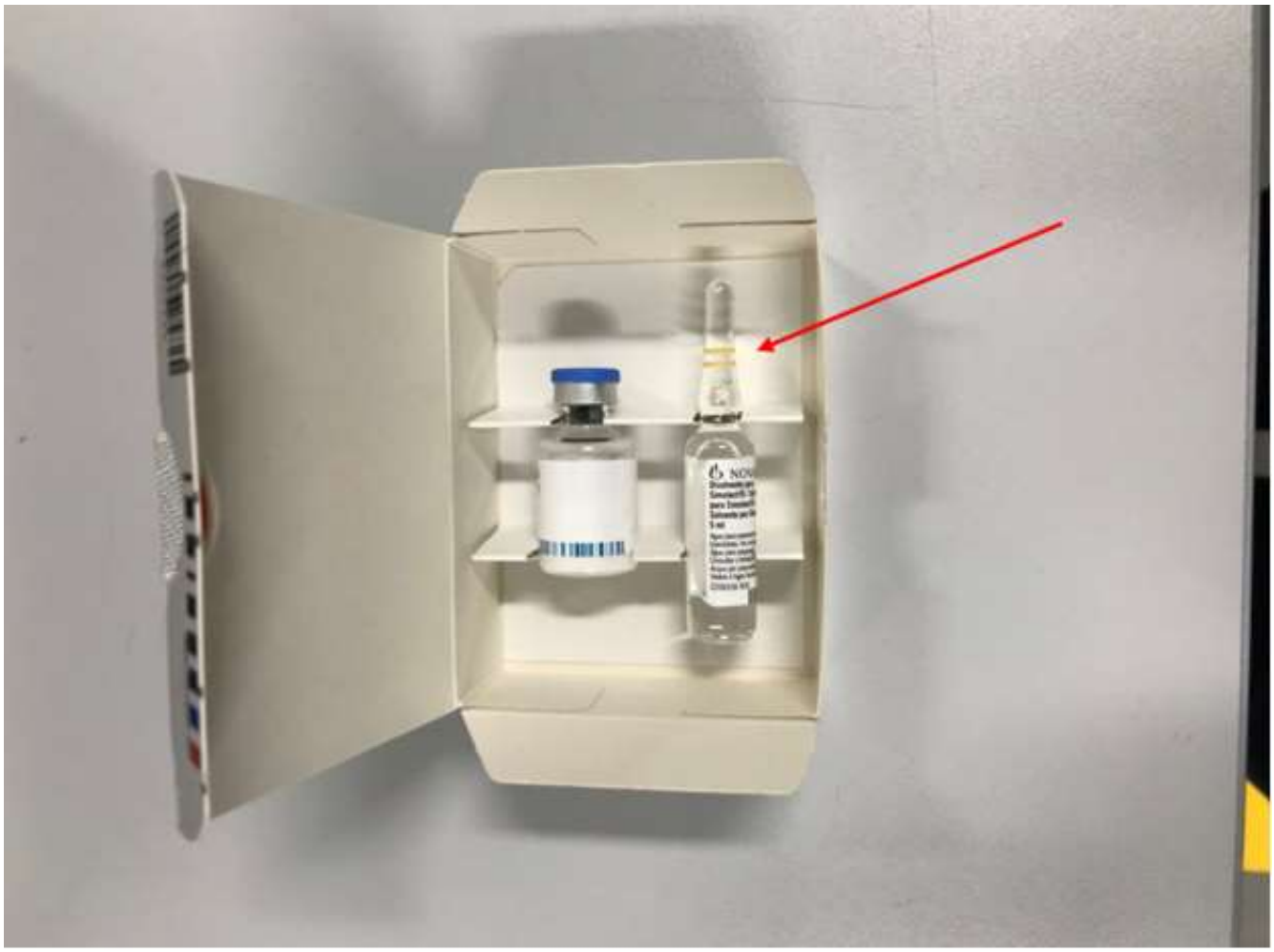
AFFECTED PRODUCT	
Water For Injection ampoules in Simulect 20 mg	**Finished product batch # SFTR2 and WFI batch # M0797** **Product Expiry: 04.2025** **Finished product batch # SHEN8 and WFI batch # M0797** **Product Expiry: 07.2025**

14 April 2023

Problem Description

Novartis identified the potential presence of process related particles (glass) in WFI ampoules co-packed with the marketed Simulect product. See Figure 1. Novartis therefore requests you **to not use the WFI ampoules co-packed with Simulect 20mg vials** but to use Medsafe-approved WFI ampoules (Water for Injections without any additives) from another source for reconstitution. See below for WFI alternate products. **Novartis is confident about the quality of Simulect vials (the vials are fully complying with specifications) and they can be administered without any associated risk by using an alternative WFI source.**

Figure 1: Presentation of impacted WFI ampoule co-packed with Simulect 20mg vials (ampoule pointed with red arrow)



Affected Products – see Customer Reply Form (Attached)

Potential risk associated

Process related particles were identified in WFI for the impacted batches during the course of an ongoing investigation and the WFI does not meet specification for particles.

Actions to be taken by Health Care Professionals

1. Health Care Professionals can continue to safely administer the affected Simulect batch listed in the Customer Reply Form (Attachment) with the prerequisite to exchange the WFI co-packed with the product with another approved WFI ampoule from an alternative source such as the ones listed below:

	Pharmacode
Water for injection, Multichem	2208326
Water for injection, Pfizer	2511932
Water for injection, Fresenius Kabi	2565692

2. Health Care Professionals are kindly asked to discard the impacted WFI ampoules co-packed batch of Simulect (listed in Customer Reply Form) at the time of opening the pack, and send Novartis the confirmation, including the number of discarded ampoules, to assure reconciliation.
3. Please complete the Customer Reply Form and return it to Novartis.

Please kindly report any quality problem or any adverse event associated with this product to CARM as per normal established processes.

Should you require any additional information please contact **Novartis Medical Information on 0800 354 335.**

This Product Alert action is being taken after consultation with Medsafe, Ministry of Health, New Zealand.

We sincerely apologise for any inconvenience this may have caused and thank you for your continued support.

Sincerely,

Helen Athanasopoulos
Country Quality Head, Australia and New Zealand
Novartis Pharmaceuticals Australia Pty Ltd.
54 Waterloo Road
Macquarie Park, NSW 2113

CUSTOMER REPLY FORM

Product Alert

Water for Injection (WFI) ampoules co-packed with Simulect 20mg

Please complete the Customer Reply Form and return it to Novartis by emailing it into the mailbox, as indicated below, **within 1 working day**. Returning the customer reply form promptly will confirm your receipt of this notification.

Product	Batch Number	Associated lot number of WFI ampoules	Quantity
Simulect 20 mg vial	**SFTR2**	**M0797**	
Simulect 20mg vial	**SHEN8**	**M0797**	

Has your organization supplied Simulect 20mg batch SFTR2 or SHEN8 to any other organization? (Yes / No) :_____

If Yes, please provide the name & contact details of the organization so Novartis can contact them: _____

_____

_____

_____

Please complete and sign this form within 1 working day. Email a scanned copy to **qa.recalls@novartis.com** as a confirmation that you have received this notification.

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

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

FROM:

Organisation	
Name	
Position	
Telephone number	
Email	
Date	
Signature	