NOVARTIS

Important Product Information:

Do not use Water for Injection (WFI) ampoules co-packed with Simulect 10mg and 20mg Lyophilized Product in Vials product

12 April 2023

Dear Health Care Professionals,

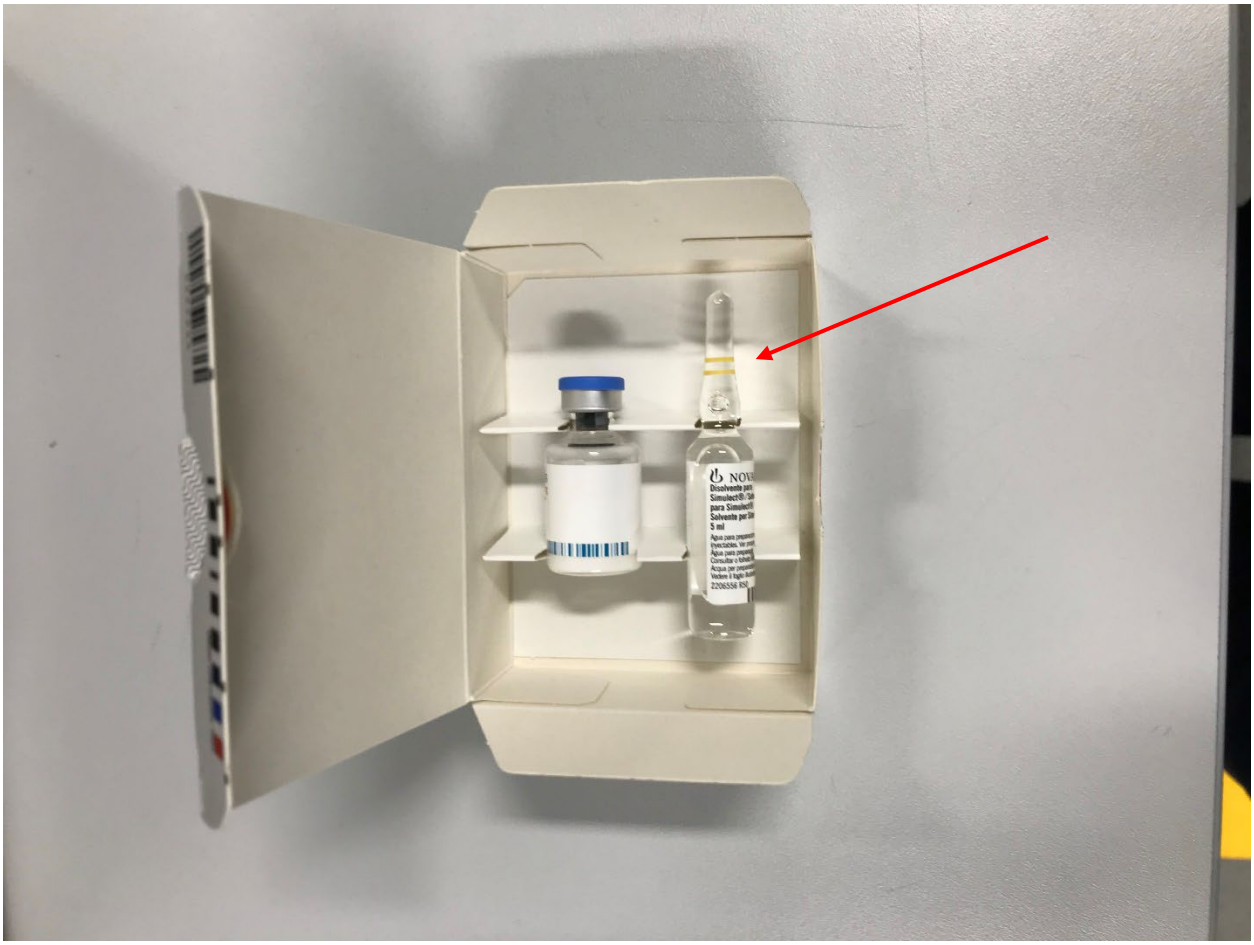
Purpose

This communication is to ask you **not to use the WFI ampoules** co-packed with Simulect 10mg and 20mg vials, but alternatively use WFI ampoules (Water for Injections compliant with European Pharmacopoeia, without any additives) from another source for reconstitution purpose. **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 (Water For Injections compliant with European Pharmacopoeia, without any additives).**

Problem Description

In course of an ongoing investigation, Novartis identified the potential presence of particles provisionally identified as small (up to 800 µm) glass fragments in WFI ampoules co-packed with marketed Simulect product. See Figure 1. Novartis therefore requests you **to not use the WFI ampoules co-packed with Simulect 10mg and 20mg vials** but to use WFI ampoules (Water for Injections compliant with European Pharmacopoeia, without any additives) from another source.

Figure 1: Presentation of impacted WFI ampoule co-packed with Simulect 10mg and 20mg vials (ampoule pointed with red arrow)



Affected Products - see Attachment

Potential risk associated

Particles provisionally identified as small (up to 800 µm) glass fragments were identified in WFI for the impacted batches in the course of the ongoing investigation.

Actions to be taken by Health Care Professionals

1. Health Care Professionals can continue to safely administer the affected Simulect batches listed in the Attachment with the prerequisite to exchange the WFI co-packed with the product with another WFI ampoule from an alternative source that complies with European Pharmacopoeia requirements for Water for Injections.
2. Health Care Professionals are requested to provide Novartis with the currently available quantity of the Simulect batches listed in the Attachment, at your premises.
3. Health Care Professionals are kindly asked to discard the impacted WFI ampoules co-packed with batches of Simulect (listed in Attachment) at the time of opening the pack, and send Novartis the confirmation, including the number of discarded ampoules, to assure reconciliation.
4. **If other facilities or departments within your hospital or clinic use this product, please forward a copy of this information to them as a matter of urgency.**
5. Please complete the enclosed Customer Reply Form (Attachment) and return it to Novartis by emailing it into the mailbox, as indicated in the Attachment, **within 1 working day**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
6. Health Authorities have been notified about this letter.
7. Please kindly report any quality problem or any adverse event associated with this product as per normal established processes.

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

Sincerely,

Muge Mert, Global Program Safety Lead

Ola Adel, Site Quality Head Stein, Switzerland