NOVARTIS

Direct Healthcare Professional Communication

02 May 2023

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

Dear Health Care Professionals,
Novartis Saudi LTD, in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Summary

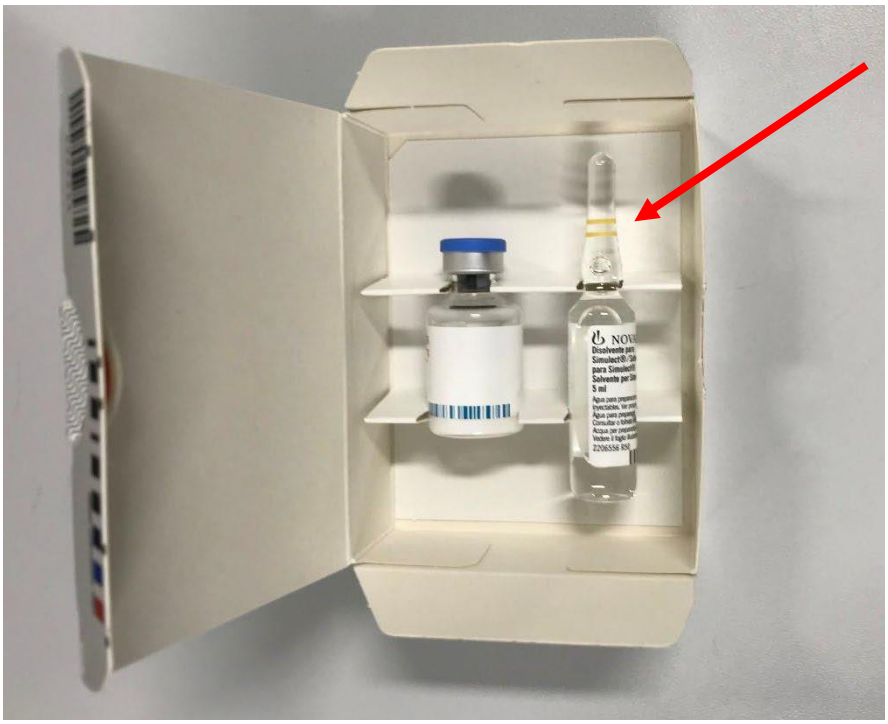
- **The purpose of this letter is to inform you of important safety information for Simulect® (basiliximab) 20mg.**
- **not to use the WFI ampoules co- packed with Simulect® (basiliximab) 20mg vials,**
- **but alternatively use WFI ampoules (Water For Injections compliant with European Pharmacopoeia, without any additives) from another source for reconstitution purpose.**

Further information on the safety concern and the recommendations

The presence of process-related particles was identified in the Water for Injection (WFI) ampules that are packed with Simulect powder (see Figure 1). The affected batch of WFI (M0797) was co-packed with Simulect 20 mg batches SFUY9, SHJA7, and SHMT7, which were distributed by Novartis. Therefore, do not to use the affected WFI ampules that are co-packed with Simulect 20 mg vials in these identified batches.
Novartis assures that the quality of Simulect vials are intact and they are compliant with specifications.

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

Affected batches (3): SFUY9, SHJA7 & SHMT7



Potential risk associated

Process related particles were identified in WFI for the impacted batches in the course of ongoing investigation.

Actions to be taken by Health Care Professionals

1. Health Care Professionals are kindly asked to discard the impacted WFI ampoules co-packed batches of Simulect (listed above) at the time of opening the pack, and send Novartis the confirmation, including the number of discarded ampoules, to assure reconciliation.
2. If other facilities or departments within your hospital or clinic use this product, please forward copy of this information to them.
3. Please complete the enclosed Customer Reply Form (Attachment) and return it to Novartis by emailing it into the mailbox, as indicated in the Attachment. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

Call for reporting

Please report any suspected adverse reactions associated with the use of **Simulect** in accordance with the national requirements to:

Novartis Saudi Ltd
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
Or by online: https://report.novartis.com/

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Email: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

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

Sincerely,

Alaa Albalawi, Quality Assurance Manager

Albalawi Alaa
Digitally signed by Albalawi Alaa
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Chedli Ghedira, Country Quality Assurance Head

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