Direct Healthcare Professional Communication

Dec 2023

SIMULECT ® (basiliximab): Supply of Simulect 20mg packs containing only basiliximab powder vial without the water for injection ampoule.

Dear Healthcare Professional,

Novartis in agreement with The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following **Supply of Simulect 20mg packs containing only basiliximab powder vial without the water for injection ampoule.**

Summary:

- Particles have been found in some ampoules of water for injection(WFI) that are co-packed with Simulect 20 mg vials. The particles are intrinsic to the WFI ampoules and do not affect the vials of Simulect.
- To avoid stock out situation at the patient level, and as a temporary measure, the current presentations of Simulect 20 mg packs containing only the powder vial (not the WFI ampoule) are being supplied to the hospitals.
- However, folding box and leaflet of these temporary supplied packs still indicate that the pack contains a WFI ampoule, although the WFI ampoule is not included.
- Therefore, the reconstitution must be performed with a WFI from an alternative source, that complies with European Pharmacopoeia requirements without any additives by the pharmacy or the hospital department prior to administration to the patient.
- Novartis is confident about the quality of vials containing Simulect powder (the vials comply fully with specifications) and that they can be administered without any associated risk by using an alternative WFI source, compliant with European Pharmacopoeia, without any additives.

Further information on the safety concern and the recommendations

Simulect is indicated for the prophylaxis of acute organ rejection in de novo renal transplantation in adult and paediatric patients. It is to be used concomitantly with ciclosporin for microemulsion- and corticosteroid-based immunosuppression or in a triple maintenance immunosuppressive regimen containing ciclosporin for microemulsion, corticosteroids and either azathioprine or mycophenolate mofetil. In the course of an ongoing investigation, Novartis identified the potential presence of intrinsic particles in WFI ampoules co-packed with marketed Simulect product.

The impacted batches were already identified, and as an immediate measure, Novartis informed the Health Authorities and distributed a Dear Healthcare Professional Communication indicating not to use the WFI ampoules co-packed with Simulect 20 mg vials but to use WFI ampoules, compliant with European Pharmacopoeia, without any additives, from another source.

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To ensure the continuity of the supply of Simulect to patients, Novartis is currently working on different alternatives to put the product back on the market as soon as possible.
In the meantime, to avoid stock out situation at patient level, Novartis, in agreement with EMA and relevant Health Authorities, is temporarily supplying the current presentation to the hospitals but without the WFI ampoule. These temporarily supplied packs of Simulect 20 mg contain only the basiliximab powder vial (but not the WFI ampoule). However, the folding boxes and leaflets of these temporary supplied packs still indicate that the pack contains a WFI ampoule, although the WFI ampoule is not included. The reconstitution of the powder must be performed with a WFI from an alternative source, that complies with European Pharmacopoeia requirements without any additives by the pharmacy or the hospital department prior to administration to the patient.
Actions to be taken by Health Care Professionals
1.Health Care Professionals can continue to safely administer Simulect batches received without the WFI ampoule. A WFI ampoule from an alternative source, that complies with European Pharmacopoeia requirements without any additives, must be used.
2.If other facilities or departments within a hospital or clinic use this product, a copy of this information should be forwarded to them.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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