2 October 2023

SIMULECT ® (basiliximab): Supply of Simulect 10 mg and 20 mg packs containing only basiliximab powder vial without the water for injection ampoule.

Dear Healthcare Professional,

Novartis, in agreement with the European Medicines Agency (EMA) and the <National Competent Authority> would like to inform you of the following:

Summary

- **Particles have been found in some ampoules of water for injection (WFI) that are co-packed with Simulect 10 mg and 20 mg vials. The particles are intrinsic to the WFI ampoules and do not affect the vials of Simulect.**
- **Consequently, WFI ampoules co-packed with Simulect 10 mg and 20 mg vials cannot be used to reconstitute Simulect powder.**
- **To avoid shortages at the patient level, and as a temporary measure, the current presentations of Simulect 10 mg and 20 mg packs containing only the powder vial (not the WFI ampoule) are being supplied to hospitals.**
- **However, the folding box and leaflet of these temporarily supplied packs still indicate that the pack contains a WFI ampoule, although the WFI ampoule is not included.**
- **Therefore, to reconstitute the powder prior to administration to the patient, the pharmacy or hospital department must use WFI from an alternative source, which complies with European Pharmacopoeia requirements, and which does not contain any additives.**
- **The vials containing Simulect powder comply fully with quality specifications. There is no risk associated with using an alternative source of WFI to reconstitute these vials, providing that the WFI complies with the European Pharmacopoeia and does not contain any additives.**

Background Information

Simulect is indicated for the prophylaxis of acute organ rejection in *de novo* allogeneic renal transplantation in adult and paediatric patients (1-17 years). It is to be used concomitantly with ciclosporin for microemulsion- and corticosteroid-based immunosuppression, in patients with panel-reactive antibodies less than 80%, 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 two identified impacted batches of WFI (M2139 and M0797) were co-packed with Simulect 10mg and 20mg vials into finished product batches distributed by Novartis (impacted batches of Simulect of EU countries and Norway are listed in table 1). The impacted batches were identified, and as an immediate measure, Novartis informed the Health Authorities and distributed a Direct Healthcare Professional Communication. If any stock remains from these batches, do not use this WFI ampoules co-packed with Simulect 10mg and 20mg vials but use WFI from an alternative source compliant with European Pharmacopoeia requirements, without any additives. The impacted batches for which the WFI ampoule needs to be replaced are listed in Table 1.

Until 07 September 2023, no cases have been retrieved with either quality complaints or any adverse events with the impacted batches from the Novartis global safety database.

To ensure the continuity of the supply of Simulect to patients, Novartis is currently working to put the product back on the market as soon as possible.

In the meantime, to avoid shortages at patient level, Novartis, in agreement with EMA and relevant Health Authorities, is temporarily supplying the current presentation to hospitals without the WFI ampoule. These packs of Simulect 10 mg and 20 mg, which will be temporarily supplied to hospitals, contain only the basiliximab powder vial but not the WFI ampoule. However, the folding boxes and leaflets of these temporarily supplied packs still indicate that the pack contains a WFI ampoule, although the WFI ampoule is not included. Prior to administration to the patient, the pharmacy or hospital department must reconstitute the powder using WFI from an alternative source, which complies with European Pharmacopoeia requirements and does not contain any additives.

Table 1

Simulect batches co-packed with WFI Batch M2139:

Material	**Batch**	**Country**
SIMULECT LYVI 20MG 1+1 AT	SHRV4	Austria
SIMULECT LYVI 20MG 1+1 BE	SHTR6	Belgium
SIMULECT LYVI 20MG 1+1 BG	SHUH3	Bulgaria
SIMULECT LYVI 20MG GLW 1+1 HR	SHTR7	Croatia
SIMULECT LYVI 20MG GLW 1+1 HR	SJCA1	Croatia
SIMULECT LYVI 20MG 1+1 R29	SHYM6	Cyprus
SIMULECT LYVI 20MG 1+1 R47	SHYM5	Czechia
SIMULECT LYVI 20MG 1+1 FRH	SHRV7	France
SIMULECT LYVI 10MG 1+1 FRH	SHWE1	France
SIMULECT LYVI 20MG 1+1 DE	SHXJ4	Germany
SIMULECT LYVI 20MG 1+1 DE	SHWC2	Germany
SIMULECT LYVI 10MG 1+1 DE	SHTU9	Germany
SIMULECT LYVI 20MG 1+1 R89	SHRN9	Ireland
SIMULECT LYVI 20MG 1+1 ITH	SHTC7	Italy
SIMULECT LYVI 20MG 1+1 NL	SHRN8	Netherlands
SIMULECT LYVI 20MG 1+1 NL	SHVJ6	Netherlands
SIMULECT LYVI 10MG 1+1 NL	SHTU8	Netherlands
SIMULECT LYVI 10MG 1+1 NL	SHXU9	Netherlands
SIMULECT LYVI 20MG GLW 1+1 R43	SHTR9	Norway
SIMULECT LYVI 20MG 1+1 PL	SHXJ1	Poland
SIMULECT LYVI 20MG 1+1 PL	SHTR8	Poland
SIMULECT LYVI 20MG 1+1 PT	SHTJ3	Portugal
SIMULECT LYVI 20MG 1+1 PT	SHWE7	Portugal
SIMULECT LYVI 20MG 1+1 R47	SHTV1	Slovakia, Czechia
SIMULECT LYVI 20MG 1+1 SI	SHTJ2	Slovenia
SIMULECT LYVI 20MG 1+1 ES	SHXX1	Spain

Simulect batches co-packed with WFI Batch M0797:

Material Short Text	**Batch**	**Country**
SIMULECT LYVI 20MG 1+1 AT	SFUR6	Austria
SIMULECT LYVI 20MG 1+1 BE	SFUJ4	Belgium

Material Short Text	Batch	Country
SIMULECT LYVI 20MG 1+1 BE	SHJR9	Belgium
SIMULECT LYVI 20MG 1+1 BG	SFWD9	Bulgaria
SIMULECT LYVI 20MG 1+1 BG	SHFV8	Bulgaria
SIMULECT LYVI 20MG 1+1 R47	SHDD4	Czechia
SIMULECT LYVI 20MG GLW 1+1 R43	SHMC6	Denmark
SIMULECT LYVI 20MG 1+1 FRH	SFYM5	France
SIMULECT LYVI 20MG 1+1 FRH	SHDL4	France
SIMULECT LYVI 10MG 1+1 FRH	SHFH8	France
SIMULECT LYVI 20MG 1+1 DE	SHHD3	Germany
SIMULECT LYVI 10MG 1+1 DE	SHET4	Germany
SIMULECT LYVI 20MG 1+1 R29	SHMM1	Greece
SIMULECT LYVI 20MG 1+1 HU	SHDD3	Hungary
SIMULECT LYVI 20MG 1+1 R89	SHLR4	Ireland, Malta
SIMULECT LYVI 20MG 1+1 R89	SHDM5	Ireland, Malta
SIMULECT LYVI 20MG 1+1 R89	SHFV1	Ireland, United Kingdom
SIMULECT LYVI 20MG 1+1 ITH	SFUJ3	Italy
SIMULECT LYVI 20MG 1+1 ITH	SHFV6	Italy
SIMULECT LYVI 20MG 1+1 R07\WST	SHPD1	Latvia
SIMULECT LYVI 20MG 1+1 NL	SFXV4	Netherlands
SIMULECT LYVI 20MG 1+1 NL	SHJV8	Netherlands
SIMULECT LYVI 10MG 1+1 NL	SFXJ2	Netherlands
SIMULECT LYVI 20MG 1+1 PL	SFXV7	Poland
SIMULECT LYVI 20MG 1+1 PT	SHDD2	Portugal
SIMULECT LYVI 20MG 1+1 PT	SHJV7	Portugal
SIMULECT LYVI 20MG 1+1 RO	SHFV7	Romania
SIMULECT LYVI 20MG 1+1 RO	SFYL9	Romania
SIMULECT LYVI 20MG 1+1 ES	SHDD5	Spain
SIMULECT LYVI 20MG 1+1 ES	SHFX7	Spain

Actions to be taken by healthcare professionals

1. Healthcare professionals can continue to safely administer Simulect batches received without the WFI ampoule. Reconstitution should be done using a WFI ampoule from an alternative source that complies with European Pharmacopoeia requirements and without any additives.

2. A copy of this information must be forwarded to other facilities or departments in a hospital or clinic that use this product.

Call for reporting

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

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>