Direct Healthcare Professional Communication

Oct 2023

Direct Healthcare Professional Communication (DHPC) for the Water for Injection(WFI) ampoules co-packed with Simulect (Basiliximab) 20mg vials, have been removed from batch number SFTR2, SHEN8, SHJW3 and an alternative WFI must be used for reconstitution.

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 **Water for Injection(WFI) ampoules co-packed with Simulect**:

Summary:

- Novartis has previously identified potential presence of process related particles in WFI ampoules co-packed with marketed Simulect product.
- The WFI ampoules co-packed with Simulect 20mg vials, have been removed from batch number SFTR2, SHEN8, SHJW3. 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.
- To avoid stock out situation at the patient level, alternatively you must use WFI (Sterilized Water for Injection B.P. 2019- 5 ml-El Fath for Drug Cosmetics Industry FIPCO, without any additives) must be used. This is provided separately by distributor and as approved by EDA.
- Novartis is confident about the quality of Simulect vials (the vials are fully complying with specifications), and the vials can be administered without any associated risks by using the alternative WFI (Sterilized Water for Injection B.P. 2019- 5 ml-El Fath for Drug Cosmetics Industry FIPCO, without any additives) provided separately by distributor.

Further information on the safety concern and the recommendations

For information about reconstituting Simulect and instruction for the use and handling, referring to the most recent local Product Information as below:

To prepare the infusion/injection solution, add 5 mL of water for injection from the accompanying ampoule aseptically to the vial containing the Simulect powder. Shake the vial gently to dissolve the powder. Use the reconstituted, colorless, clear to opalescent solution as soon as possible, but it may be stored at 2 to 8°C for 24 hours or at room temperature for 4 hours. Discard the reconstituted solution if not used within 24 hours.

➢ The reconstituted solution is isotonic and may be given as a bolus injection or diluted to a volume of 50 mL or greater with normal saline or dextrose 5% for infusion.

➢ Since no data are available on the compatibility of Simulect with other intravenous substances, Simulect should not be mixed with other medications/substances and should always be given through a separate infusion line.

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Infusion bag

- Baxter minibag NaCl 0.9%

Infusion sets

- Luer Lock, H. Noolens
- Sterile vented i.v. set, Abbott
- Infusion set, Codan
- Infusomat, Braun
- Infusionsgerät R 87 plus, Ohmeda
- Lifecare 5000 Plumset Microdrip, Abbott
- Vented basic set, Baxter
- Flashball device, Baxter
- Vented primary administration set, Imed

Further information

Compatibility with other commercial devices has not been tested.
For more information about Simulect product, please refer to the most recent local Product Information approved by EDA.
Indication: Simulect is indicated for the prophylaxis of acute organ rejection in *de novo* renal transplantation in adult and pediatric 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, corticosteroid and either azathioprine or mycophenolate mofetil.

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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