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Basiliximab (Simulect®) Warning against off-label use in cardiac transplantation

Dear healthcare professional,

Novartis wishes to remind you that Simulect® is indicated only for the prophylaxis of acute organ rejection in de novo allogeneic renal transplantation. No adequately powered randomized studies comparing Simulect to other induction agents or to the absence of induction therapy have been conducted in other transplant indications such as cardiac transplantation. Efficacy could not be demonstrated in those studies that have been conducted in cardiac transplantation, whereas there was a higher rate of serious cardiac adverse events for Simulect compared to other induction therapies.

To reflect the lack of favourable efficacy and safety data in the available clinical trials conducted in cardiac transplantation, the Summary of Product Characteristics (SmPC) will be updated as indicated below.

"Section 4.4 Special warnings and precautions for use

Heart transplantation

The efficacy and safety of Simulect for the prophylaxis of acute rejection in recipients of solid organ allografts other than renal have not been demonstrated. In several small clinical trials in heart transplant recipients, serious cardiac adverse events such as cardiac arrest (2.2%),–atrial flutter (1.9%) and palpitations (1.4 %) have been reported more frequently with Simulect than with other induction agents."

Please contact Novartis if you have any questions about this information or the safe and effective use of Simulect.

The information in this letter is being sent in agreement with the European Medicines Agency.

Further 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) (see section 4.2). 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.

Call for reporting

Healthcare professionals should report any suspected adverse reactions associated with use of Simulect in accordance with the national requirements via the national spontaneous reporting system through the national Adverse Drug Reactions (ADRs) reporting system.

Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Company contact point

Adverse reactions should also be reported to Novartis on +356 21222872 or drug_safety.malta@novartis.com.

Yours sincerely,

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