

Mycofenolaatmofetil + Belatacept

M1133

MMF = mycofenolaatmofetil (prodrug)

MPA = mycofenolzuur (actieve vorm)

Onderbouwend	Stof	Effect	Code
SPC Nulojix Assessment report Nulojix	mycofenolzuur + belatacept	bij combinatie met MMF is de blootstelling aan MPA ong. 40% hoger dan bij combinatie van MMF met ciclosporine. p. 32: hogere Cmax MPA (dose normalised) 22% en AUC 41% bij gebruik belatacept dan bij personen die ciclosporine kregen. Studie: belatacept vs ciclosporine. In beide gevallen met basiliximab inductie, MMF and corticosteroiden. Geen toename bijwerkingen.TDM niet nodig.	1A

Overig	Stof	Effect
SPC Nulojix Assessment report Nulojix	mycofenolzuur + belatacept	van belatacept wordt niet verwacht dat het de entero-hepatische recirculatie van MPA onderbreekt p.37 the circumstance that patients on belatacept (and resulting higher MPA exposure) did not show an increase in MPA-related adverse events. TDM is not warranted.
Assessment report Nulojix	belatacept	p.18 :since belatacept is a protein it does not undergo metabolism by the CYP enzymes and, thus, it is not expected to have direct PK interactions with molecules that are metabolized by these enzymes. No studies were therefore conducted to determine the potential for any drug-drug interactions of belatacept with any other molecules. p.32: no in vitro and in vivo studies have been performed. The applicant has investigated the interaction between CsA and mycophenolic acid. The Phase 3 program was composed of 2 randomized, active-controlled, partially-blinded global studies in de novo renal transplant patients receiving allografts from a broad range of donor types. Both studies evaluated 2 belatacept dose regimens, which were compared to CsA. In the studies, belatacept was administered in conjunction with basiliximab induction, MMF and corticosteroids. These adjunctive agents were also used in the comparator group. Dose normalised MPA, the active moiety of MMF, Cmax and AUC were approximately 22% and 41% higher, respectively, in subjects receiving belatacept compared to subjects receiving CsA. p. 72: MPA levels in subjects who were also taking MMF in IM103008 and IM103027 were assessed. MPA exposure was approximately 41% higher with belatacept than with CsA. CsA inhibits the enterohepatic recirculation of MPA.

Opmerkingen

SPC Cellcept, Myfortic: belatacept niet genoemd.

PubMed: 0 hits op mycophenolate mofetil and belatacept and drug interaction; verder niets bijzonders.

WFG: alleen mycofenolaatmofetil koppelen, niet op mycofenolaatnatrium.

Risicogroep	
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	Interactie	Actie	Datum
Beslissing WFG	Ja	Nee	26 juni 2012