20 September 2018
EMA/722181/2018
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): prasugrel

Procedure No. EMEA/H/C/PSUSA/00002499/201802

Period covered by the PSUR: 26 February 2017 to 25 February 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

Data from trials with ST segment elevation myocardial infarction patients and healthy individuals showed overall delayed and reduced effect of and/or decreased exposure of prasugrel in the first two hours following co-administration of morphine at the same time. The interaction disappeared within 1 day. Similar results have been seen with other P2Y12 inhibitors. The proposed mechanism of this interaction is that opioid delays gastric ventricular emptying and thus reduces absorption of prasugrel. This is a well-known effect of morphine, however this interaction is considered clinically relevant, as analgesic treatment with morphine and inhibition of platelet function with, for example, P2Y12 inhibitors may be used in acute myocardial infarction. Some of the above studies suggested that intravenous drugs may be necessary if morphine is administered and fast P2Y12 inhibition is considered crucial. Based on the data presented, update of section 4.5 in the SmPC for prasugrel is considered relevant.