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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): regorafenib

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Based on a numerically higher rate of dehydration in the regorafenib arm of clinical trials and 403 serious events reported from post-marketing sources and although it is acknowledged that the event of dehydration is secondary to other conditions (such as diarrhoea and vomiting), considering the number of reported events, the seriousness of the cases, and also in line with the information given in the SmPC of the other tyrosine kinase inhibitors, 'dehydration' should be added to the table of adverse drug reactions with the frequency 'common'.