

Initial Submission KANARB TABLETS 60 MG

Reg No. 1C 9/60 (NC)

Approval date 2 Aug 2017

Variation submission

| Application number | Scope | Approval date | Product Information affected | Summary |
|--------------------|---|---------------|---------------------------------------|---------|
| 15290/62 (N) | MiV-PA 5 : Change of batch size of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is not available] | 19 Mar 20 | Batch size of drug substance | |
| 15120/62 (N) | MiV-PA 28 Change in primary packaging material for non-sterile product a) Qualitative and quantitative composition and/or b) Type of container and/or c) Inclusion of primary packaging material Mav-15 Extension of shelf-life of the drug product | 17 Sep 2019 | | |
| 15052/60 (N) | MiV-N4 : Change of the name or address (for example: postal code, street name) of the manufacturer of drug product | 13 Dec 2017 | Label and Patient Information Leaflet | |