

Initial Submission TOPAMAX 100 mg

Reg No. 1C 212/41 (N)

Approval date 4 Jan 2000

Variation submission

| Application number | Scope | Approval date | Product Information affected | Summary |
|--------------------|---|---------------|---|---------|
| i15156/61(N) | MiV-PA3 Addition or replacement of the company or party responsible for batch release | 7 Dec 2018 | Label | |
| i15003/62 (N) | MiV-N6 Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance | 18 Jan 2019 | | |
| i15052/61 (N) | MaV-2 Change of content of product labeling | 24 May 2019 | Patient information leaflet Summary of Product Characteristics | |
| i15180/61 (N) | MiV-PA2 Change of product labeling (in accordance to country specific labeling requirement) | 8 Jul 2019 | | |
| i15074/62 (N) | non-AVG | 24 Apr 2019 | | |