

Initial Submission TOPAMAX 50 mg

Reg No. 1C 211/41 (N)

Approval date 4 Jan 2000

Variation submission

| Application number | Scope   | Approval date | Product Information affected                                      | Summary |
|--------------------|---|---------------|---|---------|
| i15156/61(N)       | <b>MiV-PA3</b> Addition or replacement of the company or party responsible for batch release                                    | 7 Dec 2018    | Label   |         |
| i15003/62 (N)      | <b>MiV-N6</b> 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)      | <b>MaV-2</b> Change of content of product labeling  | 24 May 2019   | Patient information leaflet<br>Summary of Product Characteristics |         |
| i15180/61 (N)      | <b>MiV-PA2</b> Change of product labeling (in accordance to country specific labeling requirement)                              | 8 Jul 2019    |   |         |
| i15074/62 (N)      | <b>non-AVG</b>  | 24 Apr 2019   |   |         |