

Initial Submission TOPAMAX 25 mg

Reg No. 1C 210/41 (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 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		