

Recommendations of the SEC (Neurology & Psychiatry) for Siponimod tablets 0.25mg, 1mg, and 2mg made in its 08th/24 meeting held on 24.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/24/000038 Siponimod tablets 0.25mg, 1mg, and 2mg	M/s. Dr. Reddy's Laboratories Ltd	<p>The firm presented proposal for grant of permission to manufacture and market of new drug Siponimod tablets 0.25mg, 1 mg & 2 mg along with BE study report of higher strength i.e. 2 mg and request for local Phase-III CT waiver and bioequivalence waiver for lower strength before the committee.</p> <p>After detailed deliberation, the committee noted that;</p> <ol style="list-style-type: none"> 1. Opinion from the ICMR may be sought regarding the indication under discussion for the proposed new drug Siponimod. 2. As there is no complete set of data on the prevalence of the disease and the genetic polymorphism of Secondary Progressive Multiple Sclerosis in public domain. Hence, the firm should submit the relevant data on prevalence of the disease and the genetic polymorphism of Secondary Progressive Multiple Sclerosis. <p>Accordingly, the committee recommended that the firm should submit data on prevalence and the genetic polymorphism of the disease Secondary Progressive Multiple Sclerosis for further discussion.</p>