

Expert Opinion on the Use of Cladribine Tablets in Clinical Practice for the Treatment of Relapsing Multiple Sclerosis

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Introduction: Cladribine tablets are approved in Europe for the treatment of adults with highly active relapsing multiple sclerosis (MS). In general, in the EU, product labels may be too broad to provide recommendations on individual treatment options, leaving clinicians with many unanswered practical questions. Here we describe a consensus-based programme led by international MS experts with the aim of providing practical recommendations to support physicians in the use of cladribine tablets in real-life clinical practice.

Methods: Clinical recommendations were developed using a modified-Delphi consensus methodology by a steering committee (SC) of 9 international MS experts. The SC identified practical clinical questions concerning the use of cladribine tablets and a prioritisation exercise selected the 11 most important questions to answer. Statements to address each question were drafted using evidence obtained from a comprehensive literature search, a review of available evidence, and practical experiences and expert perspectives from SC members. An additional 33 faculty were invited to answer the questions via an online platform. Consolidated answers were reviewed and incorporated into clinical recommendations by the SC. Consensus on recommendations was achieved when $\geq 75\%$ of respondents expressed an agreement score of 7–9, on a 9-point scale.

Results: Consensus was achieved on 46 out of 47 clinical recommendations ($n=34$). Consensus in the range of 90–100% was achieved on 34/46 recommendations, 10 recommendations achieved 80–90% consensus and 2 recommendations achieved 75–80% consensus. The strength of recommendations ranged from 7–9. The one statement failing to achieve consensus scored 60.6%.

Expert-agreed practical recommendations are provided on topics including: the definition of highly active disease; the patterns of treatment response and suboptimal response with cladribine tablets; and switching to and from cladribine tablets.

Conclusion: These expert recommendations provide up-to-date relevant guidance on the use of cladribine tablets in clinical practice.

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