

Restricted use of Alemtuzumab (Lemtrada®) for Multiple Sclerosis during safety review

Following new case reports of immune-mediated and vascular problems (including fatal cases) use of Lemtrada® is currently restricted, pending the results of a safety review

(https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/health-professional-communication--hpc/dhpc-lemtrada_alemtuzumab.html).

As a temporary measure, Lemtrada® should only be started in adults with relapsing-remitting multiple sclerosis (MS) that is highly active despite treatment with at least two disease-modifying therapies or where other medications cannot be used, e.g. due to contraindications. Patients who are being treated with Lemtrada® and who are benefitting from it may continue treatment after consultation with their treating physicians.

Valid from 1st August 2019, also the Bundesamt für Gesundheit (BAG) has limited the use of Lemtrada® (<http://www.spezialitätenliste.ch/ShowPreparations.aspx>). In addition to the label restriction, Lemtrada® should only be used by experienced neurologists in university hospitals, and as a reserve medication.

The author group consisting of national MS experts, the Scientific Advisory Board of the Swiss Multiple Sclerosis Society, and representatives of the Swiss Neurological Society wants to clarify that extensive experience in MS treatment, including the use of Lemtrada®, is present in different national centers, independent of their academic status. The group also wants to highlight that experience and quality in patient care is not bound to a specific academic setting. The group believes that academic status alone should not be a criterion to restrict availability of a particular treatment. However, we also agree that highly specialized medications, e.g. Lemtrada®, should be restricted to experienced centers. We are currently developing a proposal for a set of criteria that would best reflect this experience.

In order to ensure the patients' welfare and safety the MS centers will collaboratively strengthen their networks for a collegial shared patient management. Within these networks risk management, administration of Lemtrada®, if indicated, and continuous follow up and monitoring

by the neurologist initially in charge of the patient will be secured. Patients and physicians of patients with a planned Lemtrada® infusion should contact their MS centers where all necessary steps will be taken.

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