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Lemtrada for multiple sclerosis: measures to minimise risk of serious side effects

EMA's safety committee (PRAC) has recommended restrictions on the use of Lemtrada (alemtuzumab) in patients with relapsing remitting multiple sclerosis. The recommendations reflect PRAC's review of reports concerning rare but serious effects, including deaths, from immune-mediated conditions (caused by the body's defence system not working properly) and serious heart, circulation and bleeding disorders, including stroke. Immune-mediated conditions can occur many months after treatment while serious disorders of the heart, circulation and bleeding may develop within days of receiving Lemtrada.

The PRAC has recommended restricting Lemtrada for use in adults with relapsing remitting multiple sclerosis that is highly active despite adequate treatment with at least one disease-modifying therapy or if the disease is worsening rapidly with at least two disabling relapses in a year and brain-imaging showing new damage. Also, Lemtrada must no longer be used in patients with certain heart, circulation or bleeding disorders or in patients who have auto-immune disorders other than multiple sclerosis.

New measures have been recommended for identifying and promptly dealing with adverse effects that might occur after treatment with Lemtrada. It should be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions.

The PRAC has also recommended updating the physician's guide and the patient information pack with advice to minimise the risk of serious heart, circulation and bleeding disorders that may occur shortly after the infusion (drip) as well as autoimmune conditions that could occur many months after the last Lemtrada treatment.

The new recommendations replace the temporary measures issued in April 2019 while the PRAC's review was under way.

The PRAC recommendations will now be sent to EMA's human medicines committee (CHMP), which will adopt the Agency's final opinion.

More about the medicine

Lemtrada is a medicine used to treat adults with relapsing-remitting multiple sclerosis, a disease of the nerves in which the body's immune system acts incorrectly to destroy the protective sheath

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surrounding the nerve cells. Relapsing remitting means that the patient has attacks (relapses) in between periods with few or no symptoms (remissions). The medicine is used for patients with active disease. It is given by infusion (drip) into a vein.

The active substance in Lemtrada, alemtuzumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a protein called CD52 found on white blood cells of the immune system (the body's defences). By attaching to CD52, alemtuzumab causes the white blood cells to die and be replaced, thereby reducing damaging activity of the immune system.

Lemtrada was authorised in the EU in 2013. More information about the medicine is available on the EMA website: ema.europa.eu/medicines/human/EPAR/lemtrada.

More about the procedure

The review of Lemtrada was initiated on 10 April 2019 at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which made a set of recommendations. The PRAC recommendations will now be sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.