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Direct Healthcare Professional Communication

02.11.2017

Cladribine (Litak): risk of progressive multifocal leukoencephalopathy (PML)

Dear Healthcare Professional,

In agreement with the European Medicine Agency and Malta Medicine's Authority, Lipomed GmbH would like to inform you of the ongoing product information changes to reflect the following:

Summary

- **Cases of progressive multifocal leukoencephalopathy (PML), including fatal cases, have been reported with cladribine.**
- **PML diagnosis has been reported 6 months to several years after treatment with cladribine.**
- **An association between cladribine and prolonged lymphopenia was reported in several of these cases.**
- **Consider PML in the differential diagnosis for patients with new or worsening neurological, cognitive or behavioural signs or symptoms.**
- **If PML is suspected, the patients should not receive further treatment with cladribine.**

Background on the safety concern

Cladribine is a purine nucleoside analogue which acts as an antimetabolite. Medicines containing cladribine authorised for oncology indications are:

- Litak, which is indicated for hairy cell leukemia (HCL).

Since cladribine can induce myelosuppression and immunosuppression, as well as lymphopenia that can last several months, it has the potential to increase the risk of PML (a rare, potentially fatal demyelinating disease of the brain caused by reactivation of the JC virus). Cases have been reported of PML associated

with cladribine when used in oncology indications. Prolonged cladribine-induced lymphopenia may be a potential risk factor for PML. The information for healthcare professionals and patients is currently being updated.
Cladribine is also authorised for the treatment of highly active relapsing multiple sclerosis (MS). The product information for cladribine for the MS indication already includes a warning about the risk of PML.

Call for reporting

Please continue to report any suspect adverse drug reactions to the Malta Medicine's Authority on ADR Reporting www.medicinesauthority.gov.mt/adrportal

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