European Medicines Agency
Post-Authorisation Evaluation of Medicines for Human Use

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PUBLIC STATEMENT

Risk of peripheral neuropathy with Sebivo (telbivudine)

The European Medicines Agency's (EMEA) Committee for Medicinal Products for Human Use (CHMP) has recommended that new warnings be included in the product information for Sebivo (telbivudine), from Novartis Europharm Ltd. This warning is intended to inform doctors about the risk of peripheral neuropathy in patients with chronic hepatitis B who are being treated with Sebivo.

Doctors are advised to monitor patients carefully for signs of peripheral neuropathy and to reconsider treatment options if they suspect that a patient is developing peripheral neuropathy.

Sebivo is indicated for the treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis as monotherapy only.

Cases of peripheral neuropathy have been uncommonly reported in patients treated with telbivudine as monotherapy. In a clinical trial investigating the combination therapy of telbivudine 600 mg daily with pegylated interferon alfa-2a 180 µg once weekly, an increased risk of peripheral neuropathy was observed.

The CHMP, after evaluating the available data, has recommended the inclusion of the following warning in the product information for Sebivo:

Peripheral neuropathy has been uncommonly reported in telbivudine-treated patients. If peripheral neuropathy is suspected, treatment with telbivudine should be reconsidered (see section 4.8).
An increased risk of peripheral neuropathy has been observed when telbivudine and pegylated interferon alfa-2a are co-administered (see section 4.5). Such increased risk cannot be excluded for other interferons alfa (pegylated or standard). Moreover, the benefit of this combination of telbivudine with interferon alfa (pegylated or standard) is not currently established.

For further information, please contact:

Noël Wathion
Head of Unit
Post-Authorisation Evaluation of Medicines for Human Use