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EMA reviewing safety of Uptravi for pulmonary arterial hypertension

Doctors prescribing Uptravi are advised to adhere to current prescribing information

The European Medicines Agency (EMA) is reviewing the safety of Uptravi (selexipag), following the deaths of 5 patients taking the medicine in France. Uptravi is used to treat pulmonary arterial hypertension (a life-threatening condition involving abnormally high blood pressure in the arteries of the lungs). Based on a preliminary review of available data, EMA advises that Uptravi may continue to be used, both in existing and new patients, but use must be in line with the current prescribing information.

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) will further explore all available data. Once the review is completed, final conclusions will be published.

While the review is ongoing, EMA advises that doctors prescribing Uptravi carefully follow recommendations and precautions in the current prescribing information.

Patients taking Uptravi should follow their doctors' instructions and can continue treatment with the medicine. Patients who have any questions about their treatment should speak to their doctor or pharmacist.

More about the medicine

Uptravi is a medicine used for the long-term treatment of pulmonary arterial hypertension. It is authorised for use in combination with other medicines called endothelin receptor antagonists (ERAs) and/or phosphodiesterase type 5 (PDE-5) inhibitors when these medicines do not work well enough, or on its own in patients who cannot take these other treatments. The medicine was authorised centrally in the EU in May 2016. For further information about Uptravi, see here.

* The document has been updated to clarify that Uptravi may continue to be used 'both in existing and new patients'.

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More about the procedure

The review of Uptravi is being carried out in the context of a safety signal. A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation.

The review is being carried out by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines. Once the review is completed, PRAC will make any recommendations necessary to minimise risks and protect patients' health.

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