



QUESTIONS AND ANSWERS ON EXUBERA

As part of its continuous monitoring of medicines, the European Medicines Agency (EMA) has reviewed new information on a small number of cases of lung cancer seen in patients who have taken Exubera.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has concluded that it was not possible to determine whether the cases were related to the use of Exubera or not, because there were too few cases of lung cancer, all of the cases were in former smokers, and the information provided about the cases was limited. However, as a precautionary measure, the Committee has recommended that the prescribing information for Exubera be updated to include the information on these lung cancer cases.

What is Exubera?

Exubera is a fast-acting insulin powder for inhalation (breathing in). The active substance in Exubera is a copy of human insulin. Exubera is used for the treatment of adults with type 1 or type 2 diabetes. These are diseases in which the body does not produce enough insulin to control the level of blood glucose (sugar) or when the body is unable to use insulin effectively. The marketing-authorisation holder (the company that makes Exubera) is Pfizer Limited.

Pfizer stopped supplying Exubera to pharmacies on 18 January 2008 for commercial reasons. Some stocks of Exubera are still available but all patients need to switch to other diabetes medicines by September 2008, when supplies of Exubera are expected to run out.

What is the issue with Exubera?

There have been a total of seven cases of lung cancer diagnosed in patients who have taken Exubera. Five of these cases were in studies comparing Exubera with other diabetes treatments, out of 3,800 'patient-years' of exposure to the medicine. In contrast, lung cancer was diagnosed in one patient who had taken a comparator medicine, out of 3,900 patient-years of exposure. One 'patient-year' is the equivalent of one patient taking the medicine for one year.

There was also another case of lung cancer in a study where Exubera was not compared with any other treatment. The last case was reported in a patient not in a study, who received the medicine once it was on the market.

All of the lung cancer cases occurred in patients who had been cigarette smokers.

Because the number of cases is small and because they only occurred in former smokers, the CHMP could not determine whether the lung cancer cases were related to Exubera or not. However, the Committee could not exclude the possibility that there could be a relationship between Exubera and lung cancer.

What action is the EMA taking?

As a precautionary measure, the CHMP has recommended that the product information for Exubera be updated to include the new information on the lung cancer cases. This information will enable patients and their doctors to decide whether to continue using Exubera while the medicine is still available.

What will happen next?

The company that makes Exubera is planning a study to look in more detail into the possible risk of lung cancer developing in patients who have taken Exubera.

This study is expected to involve the patients who have taken part in studies of Exubera over the last five years and to follow these patients up for up to two years.
As soon as more information becomes available, the EMEA will update the information on Exubera.

What is the advice to patients and doctors?

- As supplies of Exubera will not be available in the near future, patients who are still taking it should talk to their doctor about switching to other treatments for diabetes.
- Doctors should contact any of their patients who are still taking Exubera to discuss other treatment options.
- Patients who have taken Exubera in the past and have any concerns should speak to their doctor or pharmacist.