European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

EXUBERA

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Exubera?
Exubera is a fast-acting insulin powder for inhalation (breathing in). Exubera contains 1 mg or 3 mg of the active substance human insulin.

What is Exubera used for?
Exubera is an insulin used for the treatment of adults with type 2 diabetes, when it is not properly controlled with anti-diabetes tablets. Exubera can also be used for certain adults with type 1 diabetes, who can benefit from replacing fast-acting subcutaneous insulin by this inhaled insulin, taking into account the potential risks.
The medicine can only be obtained with a prescription.

How is Exubera used?
Exubera is used only with its insulin inhaler. The insulin is contained as a powder in a blister. To take a dose, the patient places the blister in the inhaler, and inhales it through the mouth into the lungs. Before starting Exubera, a doctor or a nurse must explain to the patient how to use the inhaler properly to minimise risk and ensure that the patient gets the best benefit from their treatment. A doctor decides for each patient the starting doses and the timing of the doses, and the dose adjustment schedule. This depends on the patient's response and requirements (e.g. diet, physical activity and life-style). Exubera is given within 10 minutes before the start of a meal. A 1 mg unit dose blister gives about the same dose as an injection of 3 IU of fast-acting subcutaneous insulin and a 3 mg unit dose blister about the same as 8 IU of fast-acting subcutaneous insulin. So Exubera is not suitable when small (less than 3 IU) adjustments of insulin are necessary (for example in patient with low body weight).

How does Exubera work?
Diabetes is a disease in which the body does not produce enough insulin to control the level of blood sugar. Exubera is a replacement insulin which is identical to the insulin made by the pancreas. The insulin in Exubera is produced by a method known as 'recombinant DNA technology' which means that the insulin is made by a bacterium which has received a gene (DNA) that makes it able to produce the insulin. When inhaled, some of the insulin is absorbed into the blood (the rest is broken down in the lungs). Once in the blood, the insulin facilitates the transport of glucose into cells and helps to control the level of blood sugar. By controlling the level of blood sugar, the symptoms and complications of diabetes are reduced. Exubera works in type 1 diabetes, when the pancreas cannot produce enough insulin, and in type 2 diabetes when the body is unable to use insulin effectively.

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How has Exubera been studied?
Exubera has been studied in patients with type 2 or type 1 diabetes. In type 1 diabetes, Exubera was compared to subcutaneous (injected) insulin. In type 2 diabetes, Exubera was compared to subcutaneous insulin, and to oral anti-diabetes medicines. The studies measured the level in the blood of glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled.

What benefit has Exubera shown during the studies?
Overall, in studies in type 1 and type 2 diabetes, Exubera gave similar blood glucose control to that given by fast-acting subcutaneous human insulin.

What is the risk associated with Exubera?
The most common side effects of Exubera are hypoglycaemia (low blood glucose) and cough. If a patient smokes, the amount of insulin that is absorbed from the lungs greatly increases and this may increase the risk of hypoglycaemia. Patients must not smoke while taking Exubera. Smokers must have stopped smoking for at least 6 month before they can take Exubera. If a patient starts or resumes smoking when treated with Exubera, they must use another anti-diabetic treatment immediately. Three 1 mg doses should not be used instead of one 3 mg dose because this gives a higher insulin dose and may increase the risk of hypoglycaemia. For the full description of the side effects reported with Exubera, please see the package leaflet.
During the studies, Exubera showed a small negative effect on lung function that may disappear when Exubera is stopped. If a patient already has lung disease, it is not clear how the use of Exubera affects their lungs or how the lung disease affects the intake of insulin from the lungs. Patients with poor or unstable lung function, such as asthma, emphysema or chronic bronchitis, should not use Exubera. Exubera should not be used in people who may be hypersensitive (allergic) to human insulin or any of the other ingredients.

Why has Exubera been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that Exubera's benefits are greater than its risks in certain adult patients with diabetes when used as described in the Product information, and recommended that Exubera be given marketing authorisation.

What are the measures to minimise the risk associated with Exubera?
The company that makes Exubera will carry out studies to further test its safety, particularly in patients who might have an increased risk of side effects, such as patients with asthma or chronic obstructive pulmonary disease. They will also look at the development of insulin antibodies (proteins that are produced in response to treatment with Exubera). The company will also monitor side effects, provide educational material, and improve the design of the blister packs so that it is easier to tell the difference between the 1 mg and 3 mg doses.

Other information about Exubera:
The European Commission granted a marketing authorisation valid throughout the European Union for Exubera on 24 January 2006. The marketing authorisation holder is Pfizer Limited.

The full EPAR for Exubera is available here.

This summary was last updated in 08-2006