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Review of Kogenate Bayer/Helixate NexGen started

The European Medicines Agency (EMA) has started a review to determine whether the benefits of Kogenate Bayer and Helixate NexGen in previously untreated patients with haemophilia A continue to outweigh their risks. These medicines contain a form of a protein, human coagulation factor VIII (octocog alfa), which is needed for blood to clot normally and is lacking in patients with this bleeding disorder.

The review follows recent results from a study[1] looking at data from 574 previously untreated children with haemophilia A who were given different factor VIII products. About a third (177) of the children developed antibodies (factor VIII inhibitors) against the clotting factor used, which reduces the benefit and makes bleeding more likely. The authors concluded that children given so-called second generation full-length recombinant factor VIII products such as Kogenate Bayer/Helixate NexGen were more likely to develop antibodies than those given third generation recombinant products, whereas this increase was not seen with other recombinant or plasma-derived factor VIII products.

The EMA will re-evaluate the benefits and risks of Kogenate Bayer and Helixate NexGen in the light of this new evidence and will issue an opinion on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU.

More about the medicine

Kogenate Bayer and Helixate NexGen are identical medicines that were authorised throughout the EU on 4 August 2000. They are marketed by the same company, Bayer Pharma AG.

Kogenate Bayer and Helixate NexGen are known as second generation factor VIII products. They contain a synthetic form of factor VIII, octocog alfa, produced by a method known as 'recombinant DNA technology': it is made by cells that have received a gene (DNA), which makes them able to produce the clotting factor. The octocog alfa in these products has the same structure as natural factor VIII ('full-length'). They are used to replace the factor VIII that is lacking in patients with haemophilia A, an inherited bleeding disorder. Untreated, the deficiency of factor VIII in these patients causes bleeding problems, including bleeding into joints, muscles, and internal organs that can lead to severe damage.

[1] Gouw SC, et al; PedNet and RODIN Study Group. Factor VIII products and inhibitor development in severe hemophilia A. N Engl J Med 2013; 368: 231-9.

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Alternative products containing various forms of factor VIII are available and may be used similarly. These may be extracted from human blood ('plasma-derived') or produced as full-length recombinant products with varying exposure to other blood-derived proteins (first, second, or third generation) or may contain a shortened, but still active, recombinant form of the factor VIII molecule.

More about the procedure

The review of Kogenate Bayer and Helixate NexGen has been initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004 following the procedural steps laid out in Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendation will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for all questions concerning medicines for human use, which will adopt a final opinion.