Review of Kogenate Bayer/Helixate NexGen started

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Information on Medicinal Product

- Kogenate Bayer and Helixate NexGen are identical medicines that were authorised via the centralised procedure. They are marketed by the same company, Bayer Pharma AG. Kogenate Bayer is used in Malta.
- Kogenate Bayer and Helixate NexGen are known as second generation factor VIII products. They contain a synthetic form of the blood 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').
- Kogenate and Helixate are used to replace the factor VIII that is lacking in patients with haemophilia A, an inherited bleeding disorder. If left 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.

Information from European Medicines Agency about the safety concern

The European Medicines Agency (EMA) has started a review to determine whether the benefits of Kogenate and Helixate in previously untreated patients with haemophilia A continue to outweigh their risks. 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

[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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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.

In Malta

For Healthcare Professionals

Pending the outcome of this review, no changes to prescribing, dispensing or administering Kogenate Bayer are advised.

For more information please see the **press release** and **question-and-answers** issued by the European Medicines Agency and the current European public assessment report for Kogenate which can be found on the Agency's website: **ema.europa.eu/Find medicine/Human medicines/European public assessment reports.**

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Kogenate and Helixate. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority yellow card scheme or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.>

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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