Review of factor VIII medicines started
EMA to evaluate risk of developing inhibitors in patients starting treatment for haemophilia A

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Information on factor VIII medicine

- Factor VIII is a clotting protein and these medcines are used to temporarily increase levels of this protein in patients with haemophilia A and help to prevent and control bleeding.
- Human blood-derived factor VIII medicines are extracted from blood plasma while recombinant factor VIII products are produced by biotechnology methods.

These products include efmoroctocog alfa, moroctocog alpha, octocog alpha, simoctocog alfa, susoctocog alpha and turoctocog alfa. In Malta all products are centrally authorized except for octocog which is authorised both nationally and centrally.

Information about the review - EMA to evaluate data from recent study which compared blood-derived and recombinant factor VIII products

The European Medicines Agency (EMA) has started a review of medicines containing factor VIII to evaluate the risk of developing inhibitor proteins in patients starting treatment for haemophilia A.

- The review follows the recent publication of a study, in which the authors suggest that inhibitors develop more frequently in patients receiving factor VIII medicines made by DNA recombinant technology than in those receiving factor VIII medicines derived from blood.
- Inhibitors are a treatment challenge for both blood-derived and recombinant factor VIII medicines. They are produced by the body as a reaction to factor VIII medicines in some patients, particularly in those starting treatment for the first time, and can block the effect of these medicines, causing loss of bleeding control.
- The EMA will evaluate data from the recent study together with all other relevant data on blood-derived and recombinant factor VIII medicines and will consider the implications of

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this data for previously untreated patients with haemophilia A. The need for risk minimisation measures or other changes to the marketing authorisations of these products will also be consider

The PRAC's recommendations will be sent to Committee for Medicinal Products for Human Use (CHMP), which will issue the Agency's final opinion in due course.

While the review is ongoing, patients who have any concerns about their medication should discuss them with their healthcare professional and for more information on review of Factor VIII medicines please refer to the European Medicines Agency's press release

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on factor VIII containing medicines. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

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.

The Medicines Authority thanks you for your time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. Your feedback may be returned by folding this page address side up, stapling the ends and then posting (no stamp required)

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