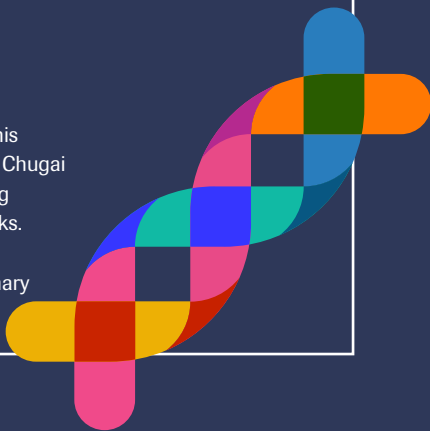
Laboratory Professional Guide

Hemlibra® ▼(emicizumab)

Subcutaneous injection for routine prophylaxis of bleeding episodes in patients with haemophilia A with factor VIII inhibitors

▼ This medicinal product is subject to additional monitoring. This educational material is provided by Roche Products Limited and Chugai Pharma UK Ltd and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

Full prescribing information can be found in the Hemlibra Summary of Product Characteristics (SmPC): www.medicines.org.uk



What is Hemlibra?

Medicinal Product

Hemlibra is a humanised monoclonal modified immunoglobulin G4 (IgG4) antibody with a bispecific antibody structure produced by recombinant DNA technology in Chinese hamster ovary (CHO) cells.

- Pharmacotherapeutic group: Antihemorrhagics, ATC code: B02BX06

Mode of Action

Hemlibra bridges activated factor IX and factor X to restore the function of missing activated factor VIII that is needed for effective haemostasis.

Hemlibra has no structural relationship or sequence homology to factor VIII and, as such, does not induce or enhance the development of direct inhibitors to factor VIII.

Pharmacodynamics

Prophylactic therapy with Hemlibra shortens the aPTT and increases the reported factor VIII activity (using a chromogenic assay with human coagulation factors). These two pharmacodynamic markers do not reflect the true haemostatic effect of Hemlibra in vivo (aPTT is overly shortened and reported factor VIII activity may be overestimated) but provide a relative indication of the pro-coagulant effect of Hemlibra.

Indication

Hemlibra is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A with factor VIII inhibitors. Hemlibra can be used in all age groups.

Laboratory coagulation test interference

Hemlibra affects assays for activated partial thromboplastin time (aPTT) and all assays based on aPTT, such as one stage factor VIII activity (see Table 1 on the next page).

Therefore, aPTT and one-stage FVIII assay test results in patients who have been treated with Hemlibra prophylaxis should not be used to assess Hemlibra activity, determine dosing for factor replacement or anti coagulation, or measure factor VIII inhibitor titers (see next page).

However, single-factor assays utilising chromogenic or immuno-based methods are not affected by Hemlibra and may be used to monitor coagulation parameters during treatment, with specific considerations for FVIII chromogenic activity assays.

Chromogenic factor VIII activity assays containing bovine coagulation factors are insensitive to Hemlibra (no activity measured) and can be used to monitor endogenous or infused factor VIII activity, or to measure anti-FVIII inhibitors. A chromogenic Bethesda assay utilising a bovine-based factor VIII chromogenic test that is insensitive to Hemlibra may be used.

Laboratory tests unaffected by Hemlibra are shown in Table 1 on the next page.

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Table 1 | Coagulation Test Results Affected and Unaffected by Hemlibra

Results Affected by Hemlibra	Results Unaffected by Hemlibra
Activated partial thromboplastin time (aPTT)	Thrombin time (TT)
Activated clotting time (ACT)	One-stage, prothrombin time (PT)-based, single-factor assays
One-stage, aPPT-based, single factor assays	Chromogenic-based single-factor assays other than FVIII[1]
aPTT-based Activated Protein C Resistance (APC-R)	Immuno-based assays (e.g. ELISA, turbidimetric methods)
Bethesda assays (clotting based) for FVIII inhibitor titers	Bethesda assays (bovine chromogenic) for FVIII inhibitor titers
	Genetic tests of coagulation factors (e.g. Factor V Leiden, Prothrombin 20210)

[1]For important considerations regarding FVIII chromogenic activity assays, see section 4.5 of the SmPC

Due to the long half life of Hemlibra, these effects on coagulation assays may persist for up to 6 months after the last dose (see section 5.2 of the SmPC).

The laboratory director should contact the Healthcare Provider to discuss any abnormal test results.

Call for reporting

For full information on all possible adverse events please see the Summary of Product Characteristics (SmPC), which are available in all EU/EEA languages on the European Medicines Agency website (www.ema.europa.eu).

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

As Hemlibra is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.

Company contact point

If you have any questions or problems:

medinfo.uk@roche.com

www.roche.co.uk

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