21-June-2020

Direct Healthcare Professional Communication (DHPC)

Subject: Emicizumab/Hemlibra® & it's known interaction with certain laboratory assays in patients who become infected with the novel corona virus that causes COVID-19

Dear Haemophilia treating HCPs,

Patient safety is Roche's highest priority. Thus in response to the SFDA request to issue this local DHCP letter, we are reaching out to you to remind you about Hemlibra® and it's known interaction with certain laboratory assays. Some of these assays may be relevant to some patients that are receiving Hemlibra® and become infected with the novel coronavirus that causes COVID-19. Given that the physicians and laboratories treating COVID-19 patients may not be familiar with Hemlibra®, we want you to be prepared to share this information in cases where it is relevant. The below information is in line with the approved local Prescribing Information (See attach).

COVID-19 is caused by a novel coronavirus, therefore knowledge about how it may affect people with haemophilia A is not well understood. Severe COVID-19 patients with or without haemophilia may develop a COVID-19 associated coagulopathy resembling disseminated intravascular coagulation (DIC) as the condition progresses.

Importantly, Hemlibra® is known to interfere with one-stage clotting assays, some of which are used to diagnose and monitor patients with DIC. The following table lists Laboratory tests affected and unaffected by Hemlibra®

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

*For important considerations regarding FVIII chromogenic activity assays, *please refer to local SmPC, section 4.5 Interaction with other medicinal products and other forms of interaction*

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While this information is known within the haemophilia community, if a patient on Hemlibra® seeks treatment due to symptoms of COVID-19 infection, we recommend the above table or information is considered, to ensure awareness of this information and to remind everyone concerned to consult the approved local Prescribing Information. The long half-life (~30 days) of Hemlibra® should also be taken into consideration in the context of clinical management. Please consult local prescribing information in all cases.

In case of Hemlibra® related medical information inquiries you may contact our medical information mailbox on: jeddah.medinfo@roche.com

Call for reporting

If you become aware of an adverse event involving any product of Roche Saudi Arabia please report in accordance with the national requirements via the national spontaneous reporting system, to:

The National Pharmacovigilance and Drug Safety Centre (NPC)

Landline: 19999
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Website: https//:ade.sfda.gov.sa

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Yours sincerely,

Doha Samargandi, Local QPPV.
Roche Products Saudi Arabia

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