

31 August 2020

### ***Update on particles identified in Hemlibra®▼ (emicizumab)***

Roche is pleased to provide an update on measures that are being taken in relation to the translucent particles that were identified in Hemlibra®▼ (emicizumab) in 2019 during a routine examination of drug product batches as part of our quality assurance systems and processes. These silicon oil and protein particles are non-toxic and, based on our ongoing assessments to date, we have not observed a safety risk to patients or an impact on the efficacy of Hemlibra. Health authorities have agreed with our assessment that the benefit/risk profile of Hemlibra remains unchanged.<sup>1</sup>

Since our last statement issued on this matter in October 2019, we have been working closely with global and local health authorities regarding the various ways to reduce or eliminate these particles in Hemlibra. Though these types of particles are common in biological manufacturing,<sup>2</sup> our priority is always to deliver the highest quality medicines to patients, and as such, Roche proposes the use of a transfer needle with a filter to give additional confidence for patients and physicians in Hemlibra's use. Filter devices are commonly used with biologics (such as antibody therapies), and other intravenously administered medicines (such as replacement factor VIII) to reduce the presence of particles in an injected solution.<sup>3,4</sup> This is one of many steps we are taking to continue to ensure the highest quality of our products; including changes to the manufacturing process with the objective to minimise the occurrence of particles in Hemlibra.

Roche is collaborating with regulatory agencies and distributors to bring this transfer needle with a filter for use with Hemlibra to markets worldwide. On 19 August 2020, the European Medicines Agency (EMA) approved this label update and authorised the use of a transfer needle with a filter for Hemlibra. A label update for the transfer needle with filter has also been submitted to the U.S. Food and Drug Administration (FDA), and we have initiated conversations with other regulatory agencies as well. We are working closely with health authorities, the haemophilia community and our supply chain partners to ensure appropriate implementation, and anticipate market availability for the new administration kits with transfer needles with a filter in the EU from the beginning of 2021. We will continue to work to ensure adequate measures are in place for global rollout of the transfer needle with a filter and will provide updates as needed.

The use of a transfer needle with a filter for the administration of Hemlibra will not change the current prescribing method of the medicine.<sup>1</sup> Physicians should consult local prescribing details for the most up-to-date information. Patients should continue to use Hemlibra with the current

transfer needle without filter until new administration kits become available through their local distributor.

Should you have any questions regarding your current prescription or the management of haemophilia, please contact your healthcare provider or local patient group. For medical enquiries in relation to Hemlibra, please contact your local Roche Medical Information contact.

▼ 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.

#### **References**

1. Roche/Genentech data on file
2. Anzengruber J, et al. Comparative analysis of marketed factor VIII products: recombinant products are not alike vis-a-vis soluble protein aggregates and subvisible particles. *Journal of Thrombosis and Haemostasis*. 2018;16:1176-1181
3. Ueda T, et al. Effects of Product Handling Parameters on Particle Levels in a Commercial Factor VIII Product: Impacts and Mitigation. *Journal of Pharmaceutical Sciences*. 2019;108:775-786
4. Ipema H, et al. Drugs to be used with a filter for preparation and/or administration. *Hospital Pharmacy* 2019;1-7