20 June, 2022

Direct Healthcare Professional Communication RECORMON® (epoetin beta)

Warning:
Increased mortality with the treatment of anaemia in patients with cancer

Dear Healthcare Professional,

Roche Products Pty Limited ("Roche") in agreement of the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan would like to inform you of a safety update to the Product Information for Recormon (epoetin beta).

Summary

- ***The TGA has recently assessed the risk of increased mortality with the use of erythropoiesis stimulating agents (ESAs), including epoetin beta, to treat anaemia in patients with cancer.***
- ***The assessment concluded that there is evidence of decreased overall survival associated with the use of ESAs in patients with cancer on the basis of international adverse event reports, the medical literature, consistency with the United States Food and Drug Administration drug labels and Health Canada product monographs for ESAs and advice from the TGA's expert Advisory Committee on Medicines.***

Background on the safety concern

Recormon is indicated

- **Treatment of symptomatic anaemia associated with chronic renal failure in adult and paediatric patients.**
- **Prevention of anaemia of prematurity in infants with a birth weight of 750 to 1500 g and a gestational age of less than 34 weeks.**
- **Treatment of symptomatic anaemia in adult patients with non-myeloid malignancies receiving chemotherapy.**
- **Increasing the yield of autologous blood from patients in a pre-donation programme. Its use in this indication must be balanced against the reported increased risk of thromboembolic events.**
- **Treatment should only be given to patients with moderate anaemia (Hb 10 - 13 g/dl [6.21 - 8.07 mmol/l], no iron deficiency) if blood conserving procedures are not available or insufficient when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males).**

The safety information pertains to the indication for the treatment of anaemia in patients with non-myeloid malignancies. Roche has been working closely with the TGA to update the Product Information to reflect this identified risk of increased mortality with the treatment of anaemia in patients with cancer. Per the approved Product Information, Healthcare Professionals should follow the guidance to treat anaemia with Recormon only when it has developed as a result of concomitantly administered chemotherapy, when blood transfusion is not

considered appropriate, and when haemoglobin levels do not exceed 120 g/L.

Safety Information added to the Product Information

The above information has been added as a boxed warning to the Product Information for Recormon:

Use in Cancer In some studies, use of Erythropoiesis Stimulating Agents (ESAs) to treat anaemia in patients with cancer has been associated with increased mortality. ESAs should only be used to treat anaemia that has developed as a result of concomitantly administered chemotherapy, and only when blood transfusion is not considered appropriate. Haemoglobin levels should not exceed 120 g/L (see section 4.4 Special Warnings and Precautions for Use).

Section 4.1 THERAPEUTIC INDICATIONS was updated as follows:

- for the treatment of anaemia in patients with non-myeloid malignancies, where anaemiadevelops as a result of concomitantly administered chemotherapy, and where blood transfusion is not considered appropriate.

Call for reporting

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of Recormon. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online to the Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan of MoH of RA via www.pharm.am and mailing vigilance@pharm.am, or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05..

You may also contact to Local person for Pharmacovigilance for Hoffmann- La Roche products in Armenia Acti Group LLC, Gayane Ghazaryan via following contacts: mob.: +374 91 796688, email: gayaneh.ghazaryan@gmail.com; or back up, Nune Karapetyan via following contacts: mob: +374 91 721153 or email: nune.karapetyan.roche@gmail.com.

You may also direct your reports to Roche Georgia LLC via following contacts: tel.: +995 322 50 6284; +995 322 50 7284 or email: georgia.safety@roche.com.

Gayane Ghazaryan Gayaneh Ghazaryan 23-июн-2022

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