Direct Healthcare Professional Communication

Dec 2023

Ramucirumab: New safety label updates in Cyramza "Ramucirumab" Patient insert leaflet

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following **New safety label updates in Cyramza "Ramucirumab" Patient insert leaflet**

Summary:

- There are some safety changes in Cyramza "Ramucirumab" Patient insert leaflet.
- EVAPHARMA's Ramucirumab is **Cyramza**

Background on the safety concern & recommendations for Health care professionals:

Regarding the method of administration take in your consideration the following precautions:

There are some safety updates in the patient insert leaflet:

- Section 6.3 "Postmarketing Experience":

  Adding (Cardiac: Heart failure) for the adverse reactions have been identified during post-approval use of CYRAMZA

- Section 8.4: "Pediatric Use": Adding the follow: The safety and effectiveness of CYRAMZA as a single agent were assessed but not established in a single-arm, multicenter, open-label study [NCT02564198] that included 23 pediatric patients aged 1 year to 16 years with relapsed or refractory solid tumors. The effect on open tibial growth plates in pediatric patients who received CYRAMZA has not been adequately studied however, one patient in this study had progressive widening of distal femoral growth plate. No other new safety signals were observed in pediatric patients.

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The pharmacokinetics (PK) for these pediatric patients was within the range of the values previously observed in adults given the same dose per body weight.

Information for healthcare professionals

Ramucirumab is a recombinant human monoclonal antibody of the immunoglobulin G subclass 1 that specifically binds to the extracellular domain of the human vascular endothelial growth factor (VEGF) receptor 2. The binding of ramucirumab to VEGF receptor 2 prevents its interaction with activating ligands (VEGF-A, VEGF-C, and VEGF-D). As a result, ramucirumab inhibits ligand-stimulated activation of VEGF receptor 2 and its downstream intracellular signalling components, including Erk1/Erk2, neutralising ligand-induced proliferation and migration of human endothelial cells.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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