Direct Healthcare Professional Communication

March 2022

Anagrelide hydrochloride: Risk of thrombosis including cerebral infarction upon abrupt treatment discontinuation

Dear Healthcare professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

• There is an increased risk of thrombotic complications, including cerebral infarction, upon abrupt anagrelide discontinuation.

• Abrupt treatment discontinuation should be avoided due to the risk of sudden increase in platelet counts and potentially fatal thrombotic complications, such as cerebral infarction.

• In the event of dosage interruption or treatment withdrawal, monitor platelet counts frequently (refer to SmPC Section 4.4).

• Advise patients how to recognize early signs and symptoms suggestive of thrombotic complications, such as cerebral infarction, and if symptoms occur to seek medical assistance.

Background information on the security concerns

Anagrelide is indicated for the reduction of elevated platelet counts in at risk patients with essential thrombocythemia who are intolerant to their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy.

A cumulative analysis of company safety database till 6 August 2021 showed 15 events of thrombotic complications, including cerebral infarction, after a recent discontinuation of anagrelide. It was concluded that cerebral infarction, along with other thrombotic complications, while being part of the pre-existing condition/indication, may also occur upon abrupt anagrelide discontinuation, inadequate dosing, or lack of effect.

The mechanism of cerebral infarction following abrupt treatment discontinuation is related to the rebound in platelet count. Platelet count typically will start to rise within 4 days after discontinuation and return to baseline levels in one to two weeks, possibly rebounding above baseline values.

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Based upon the available information, the safety information under Section 4.4 "Special Warnings and Precautions for Use" and section 4.8 "Undesirable Effects of Summary of Product Characteristics (SmPC) will be updated to reflect the latest data and recommendations.

References

1. https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professionalcommunication-dhpc-xagrid-anagrelide-hydrochloride-risk-thrombosis_en.pdf

2. https://www.bfarm.de/SharedDocs/Risikoinformationen/Pharmakovigilanz/EN/RHB/2022/rhb-xagrid.html

Call for reporting

The Egyptian Pharmaceutical Vigilance Center is reminding HCP and public to report any safety information regarding human medicinal products including adverse drug reactions, medications errors, lack of efficacy and other medicine related problems through the following contacts:

The Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451
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Hotline: 15301

Email: Pv.follow-up@edaegypt.gov.eg

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

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