HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Carbimazole – Risk of acute pancreatitis

Post-marketing reports of acute pancreatitis in association with the use of medicinal products containing carbimazole/thiamazole were identified from literature and case reports. This issue was then reviewed by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC). Although the mechanism is not fully understood, the presence of cases reporting recurrent acute pancreatitis with a decreased time to onset after re-exposure to carbimazole/thiamazole might suggest an immunological mechanism.

Carbimazole is used in the management of hyperthyroidism, in preparation for thyroidectomy in hyperthyroidism, and prior to and post radio-iodine treatment.

Immediate discontinuation is required in patients who develop pancreatitis following exposure to carbimazole and treatment should not be restarted. Affected patients should be switched to alternative treatment following an individual benefit/risk assessment. Any further re-exposure to carbimazole/thiamazole in patients who have experienced acute pancreatitis must be avoided since it may result in recurrence of life threatening acute pancreatitis.

A Direct Healthcare Professional Communication (DHPC) highlighting this issue, together with strengthened contraceptive advice regarding the use of carbimazole, was circulated to relevant healthcare professionals in 2019 by the Marketing Authorisation Holders (following approval by the HPRA) of the relevant products, and published on the HPRA website.

The product information (Summary of Product Characteristics (SmPC) and Package Leaflet (PL)) for carbimazole-containing products has been updated to reflect this information.

Key Message

- Acute pancreatitis has been reported following treatment with carbimazole/thiamazole.
- Treatment should be discontinued immediately if pancreatitis occurs following exposure to carbimazole and re-exposure must be avoided as it could result in recurrence of potentially life-threatening acute pancreatitis with decreased time to onset.
- Suspected adverse reactions should be reported to the HPRA via the available methods (www.hpra.ie/report).

**Products currently authorised in Ireland include Neomercazole and Carbimazole. Further details are available at www.hpra.ie*

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