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Prescribing tip for information



MHRA Guidance Carbimazole: Risk of Acute Pancreatitis

The Medicines and Healthcare Products Regulatory Agency (MHRA) has issued guidance regarding carbimazole and an increased risk of acute pancreatitis. If acute pancreatitis occurs during treatment with carbimazole, immediately and permanently stop treatment. Re-exposure to carbimazole may result in life-threatening acute pancreatitis with a decreased time to onset.

Background

Carbimazole is authorised for use in the management of hyperthyroidism, including preparation for thyroidectomy and treatment before and after radioiodine treatment.

Carbimazole is a prodrug that undergoes rapid metabolism to the active metabolite, thiamazole. Thiamazole (synonym methimazole) is an antithyroid agent that acts by blocking the production of thyroid hormones. Thiamazole is not authorised for use in the UK.

Risk of acute pancreatitis

An <u>EU review</u> has found post-marketing reports of acute pancreatitis associated with the use of products containing carbimazole and thiamazole. In the UK, no Yellow Card reports of acute pancreatitis associated with carbimazole treatment have been received over a period of 55 years; however, a small number of reports have been received in other countries. Although the mechanism for development of acute pancreatitis is poorly understood, the presence of cases reporting recurrent acute pancreatitis with a decreased time to onset after reexposure to carbimazole suggests a possible immunological mechanism.

Carbimazole must be immediately discontinued in patients who develop acute pancreatitis during treatment. Patients should be switched to an alternative therapy on the basis of an assessment of the individual benefits and risks.

Re-exposure to carbimazole must be avoided in patients who have previously experienced acute pancreatitis with carbimazole or thiamazole as re-exposure may result in recurrence of potentially life-threatening acute pancreatitis, with a decreased time to onset. The product information for products containing carbimazole is being updated to include risk of acute pancreatitis.

Advice for healthcare professionals:

- cases of acute pancreatitis have been reported very infrequently during treatment with carbimazole;
- if acute pancreatitis occurs, stop carbimazole treatment immediately;
- do not use carbimazole in patients with a history of acute pancreatitis in association with previous treatment;
- · re-exposure may result in life-threatening acute pancreatitis with a decreased time to onset;
- report suspected adverse drug reactions to the <u>Yellow Card Scheme</u> immediately.

Reference:

1. https://www.gov.uk/drug-safety-update/carbimazole-risk-of-acute-pancreatitis accessed 20/03/19

To contact the Medicines Optimisation Team please phone 01772 214302

