NHS
Midlands and Lancashire
Commissioning Support Unit

Prescribing tip for actioning by practice team

MHRA Guidance: Carbimazole - Increased Risk of Congenital Malformations; Strengthened Advice on Contraception

The Medicines and Healthcare products Regulatory Agency (MHRA) have issued guidance regarding carbimazole which is associated with an increased risk of congenital malformations, especially when administered in the first trimester of pregnancy and at high doses.[1] Women of childbearing potential should use effective contraception during treatment with carbimazole.

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 congenital malformations

Adequate treatment of hyperthyroidism in pregnant women prevents serious maternal and foetal complications.

Carbimazole crosses the placental barrier and can cause foetal harm. An EU review of available evidence from epidemiological studies and case reports concluded there was evidence that carbimazole is associated with an increased risk of congenital malformations, especially when administered in the first trimester of pregnancy and at high doses (15 mg or more of carbimazole daily).

Reported malformations include aplasia cutis congenita (absence of a portion of skin, often localised on the head), craniofacial malformations (choanal atresia; facial dysmorphism), defects of the abdominal wall and gastrointestinal tract (exomphalos, oesophageal atresia, omphalo-mesenteric duct anomaly), and ventricular septal defect.

Advice for healthcare professionals:

- carbimazole is associated with an increased risk of congenital malformations when used during pregnancy, particularly in the first trimester of pregnancy and at high doses (15 mg or more of carbimazole daily);
- women of childbearing potential should use effective contraception during treatment with carbimazole – see FSRH statement on contraception for women using known teratogenic drugs or drugs with potential teratogenic effects.
- carbimazole should only be considered in pregnancy after a thorough individual assessment of benefits and risks of treatment, and only at the lowest effective dose without additional administration of thyroid hormones; close maternal, foetal and neonatal monitoring is recommended;
- please report to the Yellow Card Scheme any suspected adverse reactions associated with medicines taken during pregnancy experienced by women or the baby or child.

Reference:

1. https://www.gov.uk/drug-safety-update/carbimazole-increased-risk-of-congenital-malformations-strengthened-advice-on-contraception accessed 20/03/19

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