Direct Healthcare Professional Communication

Carbimazole 2.5mg/ml Oral Solution (Rosemont Pharmaceuticals)

Carbimazole or thiamazole (synonym: methimazole)-containing products: Risk of acute pancreatitis and strengthened advice on contraception

IMPORTANT: This communication contains important safety information regarding the product and **appropriate management of the important selected risks. It should be read carefully before prescribing the product.**

Prescribers to be aware of new/strengthened advice on Carbimazole (Rosemont Pharmaceuticals): Risk of acute pancreatitis and contraception guidance

Dear Healthcare professional.

Rosemont Pharmaceuticals, in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- ***Risk of acute pancreatitis***

Acute pancreatitis has been reported following treatment with carbimazole/thiamazole.
If acute pancreatitis occurs, treatment with carbimazole/thiamazole should be discontinued immediately.
As re-exposure may result in recurrence of acute pancreatitis, with decreased time to onset, these medicines must not be given to patients with a history of acute pancreatitis that occurred following administration of carbimazole/thiamazole.

- ***Strengthened advice on contraception***

A new review of available evidence from epidemiological studies and case reports strengthens the evidence that carbimazole/thiamazole is suspected to cause congenital malformations when administered during pregnancy, particularly in the first trimester of pregnancy and at high doses.
Women of childbearing potential have to use effective contraceptive measures during treatment with carbimazole/ thiamazole.
Hyperthyroidism in pregnant women should be adequately treated to prevent serious maternal and foetal complications.
Carbimazole/thiamazole must only be administered during pregnancy after a strict individual benefit/risk assessment and only at the lowest effective dose without additional administration of thyroid hormones.
If carbimazole/thiamazole is used during pregnancy, close maternal, foetal and neonatal monitoring is recommended.

Background on the safety concern

General information

Medicinal products containing carbimazole or thiamazole are used in the management of hyperthyroidism, preparation for thyroidectomy in hyperthyroidism and therapy prior to and post radioiodine treatment.
Carbimazole is a prodrug which undergoes rapid metabolism to the active metabolite, thiamazole. Thiamazole is an antithyroid agent that acts by blocking the production of thyroid hormones.

Risk of acute pancreatitis

There have been post-marketing reports of acute pancreatitis with the use of medicinal products containing carbimazole/thiamazole.
While the mechanism is poorly 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.
Immediate discontinuation of medicinal products containing carbimazole/thiamazole is required in patients who develop acute pancreatitis following exposure to carbimazole or thiamazole. Carbimazole/thiamazole must not be restarted and affected patients should be switched to an alternative therapy on the basis of the individual benefit/risk assessment.
Any future re-exposure to carbimazole/thiamazole in patients who have experienced acute pancreatitis with carbimazole or thiamazole in the past must be avoided, since it may result in recurrence of potentially life-threatening acute pancreatitis, with decreased time to onset.
The product information for medicinal products containing carbimazole/thiamazole will be updated accordingly.

Strengthened advice on contraception

A new review of available evidence from epidemiological studies and case reports strengthens the evidence that carbimazole/thiamazole is associated with an increased risk of congenital malformations, especially when administrated in the first trimester of pregnancy and at high doses.
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.

Recommendations

It is therefore recommended that women of childbearing potential use effective contraceptive measures during treatment with carbimazole/thiamazole.
The use of carbimazole/thiamazole during pregnancy should be preserved for the situations in which a definitive therapy of the underlying disease (thyroidectomy or radioiodine treatment) was not suitable prior to pregnancy and in case of new occurrence or reoccurrence during pregnancy.
Carbimazole/thiamazole must only be administered during pregnancy after a strict individual benefit/risk assessment and only at the lowest effective dose without additional administration of thyroid hormones.
If carbimazole/thiamazole is used during pregnancy, close maternal, foetal and neonatal monitoring is recommended.
The product information for medicinal products containing carbimazole/thiamazole will be updated accordingly.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

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