

Class effects of proton-pump inhibitors (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, rabeprazole, pantoprazole) on magnesium blood levels in long-term users

Final SmPC and PL wording agreed by PhVWP December 2011

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SUMMARY OF PRODUCT CHARACTERISTICS

4.4. Special warnings and precautions for use

Hypomagnesaemia

Severe hypomagnesaemia has been reported in patients treated with PPIs like <active substance> for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness and ventricular arrhythmia can occur but they may begin insidiously and be overlooked. In most affected patients, hypomagnesaemia improved after magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics), health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

4.8. Undesirable effects

Metabolism and nutritional disorders

Frequency not known: hypomagnesaemia. [*See Special warnings and precautions for use (4.4)*]

PACKAGE LEAFLET

4. Possible side effects

Frequency not known

If you are on <medicine> for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.