Consumer Update April 2022

PPIs risks of hypomagnesemia and severe cutaneous adverse drug reactions

EDA performs label update to include the following:

4.4 Special warnings and precautions for use

The following additional risks are considered relevant for long-term use:

Hypomagnesaemia

Severe hypomagnesaemia has been rarely reported in patients treated with proton pump inhibitors (PPIs) like pantoprazole 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. Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia. In most affected patients, hypomagnesaemia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaemia) improved after magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with digoxin or medicinal products 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 nutrition disorders

Not known

Hyponatremia; Hypomagnesaemia; Hypocalcemia; Hypokalemia.

Skin and subcutaneous tissue disorders

Not known

Stevens-Johnson syndrome; Lyell syndrome; Erythema multiforme; Photosensitivity; Drug reaction with eosinophilia and systemic symptoms (DRESS) Subacute cutaneous lupus erythematosus.

Background on the safety concerns

PPIs are indicated in patients 12 years of age and older for:

Healing of all grades of erosive esophagitis.

Maintenance of healed EE and relief of heartburn.

Treatment of symptomatic non-erosive gastroesophageal reflux disease.

References:

1. *EMA* *(Click here)*
2. *FDA* *(Click here)*