

## SPINE SAFETY CAUTIONARY NOTICE:

### **Information for Healthcare Professionals: Nexium (esomeprazole magnesium) for delayed-release oral suspension, delayed-release capsules and (esomeprazole sodium) for injection: Labeling Changes**

According to MedWatch, FDA notified healthcare professionals of labeling changes for Nexium (esomeprazole magnesium) for delayed-release oral suspension, delayed-release capsules and (esomeprazole sodium) for injection. The following has been added to the labeling:

This information pertains to the risk of hypomagnesemia related to the use of proton pump inhibitors (PPIs) for at least three months, and in most cases after a year.

## **WARNING AND PRECAUTIONS**

### ***Hypomagnesemia***

- Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treated with proton-pump inhibitors PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesemia required magnesium replacement and discontinuation of the proton pump inhibitors PPI.
- For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), health care professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically thereafter.
- information regarding interactions with diagnostic investigations for neuroendocrine tumors, and concomitant use with St. John's Wort or rifampin

## **DRUG INTERACTIONS**

- information regarding interactions with diagnostic investigations for neuroendocrine tumors, and concomitant use with tacrolimus, digoxin, and St. John's Wort or rifampin

## **ADVERSE REACTIONS**

### ***Postmarketing Experience***

Metabolism and Nutritional Disorders:

- hypomagnesemia

## **PATIENT COUNSELING INFORMATION**

- Advise patients to immediately report and seek care for any cardiovascular or neurological symptoms including palpitations, dizziness, as these may be signs of hypomagnesemia.

## **FDA-APPROVED PATIENT LABELING**

### ***What should I tell my doctor before taking a proton pump inhibitor (PPI)?***

Before you take a PPI, tell your doctor if you:

- have been told that you have low magnesium levels in your blood

### ***What are the possible side effects of a PPI?***

Low magnesium levels in your body. This problem can be serious. Low magnesium can happen in some people who take a proton pump inhibitor medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium. Tell your doctor right away if you have any of these symptoms of low magnesium levels:

- seizures
- dizziness
- abnormal or fast heart beat, or skipped heartbeat
- jitteriness
- jerking movements or shaking (tremors)
- muscle weakness
- spasms of the hands and feet
- cramps or muscle aches
- spasm of the voice box
- Your doctor may check the level of magnesium in your body before you start taking a PPI, or during treatment; or if you will be taking a PPI for a long period of time.

## **PATIENT PACKAGE INSERT (oral only)**

### ***“What Should I Tell my Doctor Before Taking Nexium”***

- addition of St. John’s Wort (*Hypericum perforatum*) and Rifampin to the medication list

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at

<http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.