Please join us for a discussion on:

Zypitamag™
(pitavastatin) tablets

Statin intolerance and lipid management

INDICATION: ZYPITAMAG is indicated as an adjunctive therapy to diet in adult patients with primary hyperlipidemia or mixed dyslipidemia to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).

PROGRAM INFO
Thursday, November 19, 2020
6:30 PM EST

PRESENTED BY
Janice Kim, Medical Science Liaison
Raj Sidhu, Florida Product Specialist

VIRTUAL MEETING INFORMATION
URL: https://us02web.zoom.us/webinar/register/WN_1IPGD3KSRXmFCgaytArG5A
Meeting ID: 842 0079 1370
Please register using the link above.

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IMPORTANT SAFETY INFORMATION FOR ZYPITAMAG (PITAVASTATIN) TABLETS

INDICATIONS & USAGE: **ZYPITAMAG** is indicated as an adjunctive therapy to diet in adult patients with primary hyperlipidemia or mixed dyslipidemia to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C). **Limitations of Use:** The effect of **ZYPITAMAG** on cardiovascular morbidity and mortality has not been determined.

CONTRAINDICATIONS: **ZYPITAMAG** is contraindicated in patients with a known hypersensitivity to product components, in patients with active liver disease (which may include unexplained persistent elevations in hepatic transaminase levels), in women who are pregnant or may become pregnant, in nursing mothers, or in co-administration with cyclosporine.

WARNINGS & PRECAUTIONS

Myopathy and Rhabdomyolysis: Risk factors include age 65 and greater, renal impairment, inadequately treated hypothyroidism, concomitant use of certain drugs, and higher doses of **ZYPITAMAG**. **ZYPITAMAG** is contraindicated in patients taking cyclosporine and not recommended in patients taking gemfibrozil. The following drugs when used concomitantly with **ZYPITAMAG** may also increase the risk of myopathy and rhabdomyolysis: lipid-modifying dosages of niacin (>1 g/day), fibrates, and colchicine. Discontinue **ZYPITAMAG** if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Temporarily discontinue **ZYPITAMAG** in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis; e.g., sepsis; shock; severe hypovolemia; major surgery; trauma; severe metabolic, endocrine, or electrolyte disorders; or uncontrolled epilepsy. Inform patients of the risk of myopathy and rhabdomyolysis when starting or increasing the **ZYPITAMAG** dosage. Instruct patients to promptly report any unexplained muscle pain, tenderness or weakness particularly if accompanied by malaise or fever.

Immune-Mediated Necrotizing Myopathy (IMNM): There have been rare reports of IMNM, an autoimmune myopathy, associated with statin use. IMNM is characterized by: proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; positive anti-HMG CoA reductase antibody; muscle biopsy showing necrotizing myopathy; and improvement with immunosuppressive agents.

Hepatic Dysfunction: Increases in serum transaminases can occur. Rare postmarketing reports of fatal and non-fatal hepatic failure have occurred. Consider liver enzyme testing before initiating therapy and as clinically indicated thereafter. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue **ZYPITAMAG**.

Increases in HbA1c and Fasting Serum Glucose Levels: Increases of each have been reported with statins, including **ZYPITAMAG**. Optimize lifestyle measures, including regular exercise, maintaining a healthy body weight, and making healthy food choices.

ADVERSE REACTIONS: The most frequent adverse reactions (rate ≥ 2%) are myalgia, back pain, diarrhea, constipation and pain in extremity. This is not a complete list of all reported adverse events.

For additional information, **refer to full Prescribing Information at ZYPITAMAG.com**. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.FDA.gov/medwatch** or call **1-800-FDA-1088**

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