ZORVOLEX™ | The *First* Lower-Dose NSAID *Using* SoluMatrix Fine Particle Technology™

YOU ARE CORDIALLY INVITED TO ATTEND AN UPCOMING PROMOTIONAL SPEAKER PROGRAM ENTITLED:

The First Lower-Dose NSAID Using SoluMatrix Fine Particle Technology™

PRESENTED BY:

Abraham Peringol, MD
Vice Chair, Dept. of Family Medicine
West Houston Medical Center
Houston, TX

Date & Time:
Tuesday, May 27, 2014
6:30 PM CST

AT:

Antica Osteria
The Wine Room
2311 Bissonet St.
Houston, TX 77057
DINNER WILL BE SERVED.

This program is intended to introduce a new treatment option for the management of mild to moderate acute pain in adults.

RSVP to cme_rsvp@yahoo.com by May 20, 2014

Attendees should plan to arrive by the designated start time and remain through the duration of the program.

Notice: This event is conducted in accordance with the PhRMA Code on Interactions with Healthcare Professionals (HCPs) and is limited to invited HCPs and appropriate HCP staff. Attendance by guests or spouses is not appropriate.
State and Federal Employees: State and federal laws and regulations may limit your ability to receive meals. By attending this event, you confirm that you have obtained any necessary approvals from your employer.
Public Disclosures: The cost of meals provided to U.S. HCPs is subject to Iroko's national public disclosure policy as well as applicable state law disclosures.
State Law Restrictions: Regardless of where you practice or reside, if you are an HCP who is licensed in Vermont, or Minnesota, or an employee/agent of a Vermont HCP (eg, PAs, non-prescribing nurses, etc.), you may not attend this event

ZORVOLEX™ 18 mg 35 mg
(diclofenac) capsules

Indication

ZORVOLEX™ is a nonsteroidal anti-inflammatory drug (NSAID) indicated for treatment of mild to moderate acute pain in adults.

Important Safety Information

Cardiovascular Risk
Nonsteroidal anti-inflammatory drugs (NSAIDs) may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

ZORVOLEX™ is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk
NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

ZORVOLEX™ is contraindicated in patients with: a known hypersensitivity to diclofenac or its inactive ingredients; a history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.

ZORVOLEX™ should be used at the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

Elevation of one or more liver tests may occur during therapy with ZORVOLEX™. Physicians should measure transaminases (ALT and AST) periodically in patients receiving long-term therapy with ZORVOLEX™. ZORVOLEX™ should be discontinued immediately if abnormal liver tests persist or worsen.

NSAIDS, including ZORVOLEX™, can lead to the new onset or worsening of existing hypertension, which may contribute to the increased incidence of cardiovascular events. Blood pressure should be monitored closely during treatment with ZORVOLEX™. NSAIDs may diminish the antihypertensive activity of thiazides, loop diuretics, ACE inhibitors and angiotensin II antagonists.

Fluid retention and edema have been observed in some patients taking NSAIDs. ZORVOLEX™ should be used with caution in patients with fluid retention or heart failure.

Long-term administration of NSAIDs can result in renal papillary necrosis and other renal injury. ZORVOLEX™ should be used with caution in patients at greatest risk of this reaction, including the elderly, those with impaired renal function, heart failure, liver dysfunction, and those taking diuretics and ACE inhibitors. Treatment with ZORVOLEX™ in patients with advanced renal disease is not recommended.

Anaphylactoid reactions may occur in patients with the aspirin triad or in patients without prior exposure to ZORVOLEX™ and should be discontinued immediately if an anaphylactoid reaction occurs.

NSAIDs can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. ZORVOLEX™ should be discontinued if rash or other signs of local skin reaction occur.

Starting at 30 weeks' gestation, ZORVOLEX™ and other NSAIDs should be avoided by pregnant women as premature closure of the ductus arteriosus in the fetus may occur.

Concomitant administration of diclofenac and aspirin or anticoagulants is not generally recommended because of the risk of increased GI bleeding higher than users of either drug alone.

Most common adverse reactions in clinical trials (incidence ≥2%) include: edema, nausea, headache, dizziness, vomiting, constipation, pruritus, flatulence, pain in extremity, and dyspepsia.

ZORVOLEX™ capsules do not result in an equivalent systemic exposure to diclofenac as other oral formulations. Therefore, do not substitute similar dosing strengths of other diclofenac products for ZORVOLEX™.

Please see full Prescribing Information for additional important safety and dosing information.

SoluMatrix Fine Particle Technology™ is a trademark of iCeutica Pty Ltd, and is licensed to Iroko for exclusive use in NSAIDs.