Medtronic

PRESS RELEASE

Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone®

HAZELWOOD, Mo.--(BUSINESS WIRE)--Aug. 23, 2012-- Mallinckrodt, the Pharmaceuticals business of Covidien (NYSE: COV), today announced that it has entered into an agreement with Xanodyne Pharmaceuticals to purchase Roxicodone® (oxycodone hydrochloride tablets USP) in 5, 15 and 30 mg dosage strengths. Roxicodone, currently marketed in the United States, is an immediate release formulation of oxycodone indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate. With this agreement, Mallinckrodt acquires all rights to the Roxicodone New Drug Application (NDA). No financial details were disclosed.

"We are excited about this agreement as it complements our existing portfolio of opioids and leverages our pain management expertise," said Mark Trudeau, President, Pharmaceuticals. "More importantly, we are committed to safe and effective use of all of our products along with ensuring access for all patients in need of pain treatment."

Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top 10 generic pharmaceuticals manufacturers in the U.S., based on prescriptions. Its branded portfolio includes EXALGO® (hydromorphone HCl) Extended-Release Tablets (CII) and PENNSAID® (diclofenac sodium topical solution) 1.5% w/w. Mallinckrodt is also one of the world's leading producers of bulk acetaminophen.

Covidien announced last December that the Company planned to spin off Mallinckrodt into a stand-alone company, a process that is expected to be completed in mid-2013.

IMPORTANT RISK INFORMATION

About ROXICODONE

Roxicodone tablets are contraindicated in patients with known hypersensitivity to oxycodone, or in any situation where opioids are contraindicated. This includes patients with significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment) and patients with acute or severe bronchial asthma or hypercarbia. Oxycodone hydrochloride tablets are contraindicated in any patient who has or is suspected of having paralytic ileus.

Serious adverse reactions that may be associated with Roxicodone tablets therapy include: respiratory depression, respiratory arrest, circulatory depression, cardiac arrest, hypotension, and/or shock. Common adverse events that may be associated with Roxicodone tablets therapy include: nausea, constipation, vomiting, headache, pruritus, insomnia, dizziness, asthenia, and somnolence.

About EXALGO

INDICATION

EXALGO® (hydromorphone HCl) Extended-Release Tablets (CII) is indicated for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time.

WARNING: ABUSE POTENTIAL, LIFE-THREATENING RESPIRATORY DEPRESSION, and ACCIDENTAL EXPOSURE

Abuse Potential

EXALGO contains hydromorphone, an opioid agonist and a Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit. Assess each patient's risk for opioid abuse or addiction prior to prescribing EXALGO.

The risk for opioid abuse is increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depressive disorder). Routinely monitor all patients receiving EXALGO for signs of misuse, abuse, and addiction during treatment.

Life-threatening Respiratory Depression

Respiratory depression, including fatal cases, may occur with use of EXALGO, even when the drug has been used as recommended and not misused or abused. EXALGO is for use in opioid tolerant patients only. Proper dosing and titration are essential and EXALGO should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. Monitor for respiratory depression, especially during initiation of EXALGO or following a dose increase. Crushing, dissolving, or chewing the tablet can cause rapid release and absorption of a potentially fatal dose of hydromorphone.

Accidental Exposure

Accidental ingestion of EXALGO, especially in children, can result in a fatal overdose of hydromorphone.
EXALGO is contraindicated in:
Opioid non-tolerant patients. Fatal respiratory depression could occur in patients who are not opioid tolerant.
Patients with significant respiratory depression
Patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
Patients with known or suspected paralytic ileus
Patients who have had surgical procedures and/or underlying disease resulting in narrowing of the gastrointestinal tract, or have "blind loops" of the gastrointestinal tract or gastrointestinal obstruction
Patients with hypersensitivity (e.g., anaphylaxis) to hydromorphone or sulfite-containing medications
Serious adverse events could also include hypotensive effects, GI effects, cardiac arrest from overdose and precipitation of withdrawal. Most common adverse events (>10%) seen in clinical studies (N=2474) were: constipation (31%), nausea (28%), vomiting, somnolence, headache, asthenia and dizziness.

About PENNSAID

PENNSAID is a nonsteroidal anti-inflammatory drug ("NSAID") indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).

WARNING: CARDIOVASCULAR AND GASTROINTESTINAL RISK

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.

• PENNSAID is contraindicated in the perioperative 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.

PENNSAID is also contraindicated in patients:
With known hypersensitivity to diclofenac sodium or any other component of PENNSAID.
Who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions have been reported in these patients.

Anaphylactoid reactions may occur in patients without prior exposure to PENNSAID. NSAIDs can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrosis (TEN), which can be fatal.

The most common treatment-related adverse events in patients receiving PENNSAID were application site skin reactions including dry skin (32%), contact dermatitis characterized by skin erythema and induration (9%), contact dermatitis with vesicles (2%) and pruritus (4%). In a long term safety study, contact dermatitis occurred in 13% and contact dermatitis with vesicles in 10% of patients, generally within the first 6 months of exposure, leading to a withdrawal rate for an application site event of 14%. Other common adverse events greater than placebo include: dyspepsia (8%), abdominal pain (6%), flatulence (4%), diarrhea (4%) and nausea (4%).

ABOUT COVIDIEN

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2011 revenue of $11.6 billion, Covidien has 43,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Mallinckrodt, the Pharmaceuticals business of Covidien, manufactures active pharmaceutical ingredients, including bulk acetaminophen, opioid pain medications, nuclear and contrast media diagnostic agents. Sales in 2011 were $2.0 billion. Please visit www.covidien.com to learn more about our business.

Source: Covidien

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