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Percodan (aspirin/oxycodone) - Drug Summary

Endo Pharmaceuticals Inc.

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Percodan (aspirin/oxycodone)

COMMON BRAND NAMES

Endodan, Percodan

THERAPEUTIC CLASS

Opioid analgesic

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Moderate to Moderately Severe Pain

Usual: 1 tab q6h prn
Max: 4g/day of aspirin or 12 tabs/day

DOSING CONSIDERATIONS

Discontinuation
In patients who have been treated for more than a few weeks, taper gradually; do not d/c abruptly

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: (ASA/Oxycodone HCl) 325mg/4.8355mg* *scored

CONTRAINDICATIONS

Known hypersensitivity to oxycodone or aspirin. ASA: Hemophilia, children/teenagers with viral infections, NSAID allergy, and syndrome of asthma, rhinitis, and nasal polyps. Oxycodone: Significant respiratory depression (in unmonitored settings or absence of resuscitative equipment), acute/severe bronchial asthma or hypercarbia, and known/suspected paralytic ileus.

WARNINGS/PRECAUTIONS

Oxycodone: May be abused in a manner similar to other opioid agonists. May cause respiratory depression; extreme caution with acute asthma, chronic obstructive pulmonary disorder, cor pulmonale, or preexisting respiratory impairment. Respiratory depressant effects may be markedly exaggerated in the presence of head injury, other intracranial lesions, or preexisting increased intracranial pressure. Produces effects on pupillary response and consciousness, which may obscure neurologic signs of worsening in patients with head injuries. May cause severe hypotension; caution in circulatory shock. May produce orthostatic hypotension in ambulatory patients. Caution with CNS depression, hypothyroidism, Addison's disease, prostatic hypertrophy, urethral stricture, acute alcoholism, delirium tremens, kyphoscoliosis with respiratory depression, myxedema, toxic psychosis, severe hepatic/pulmonary/renal impairment, and in elderly/debilitated. May obscure diagnosis or clinical course of acute abdominal conditions. May induce or aggravate convulsions/seizures. Monitor for decreased bowel motility in postoperative patients. May cause spasm of the sphincter of Oddi; caution with biliary tract disease, including acute pancreatitis. Physical dependence and tolerance may occur. ASA: May inhibit platelet function. GI side effects reported; monitor for signs of ulceration and bleeding. May cause gastric mucosal irritation and bleeding; avoid with history of active peptic ulcer disease. May cause elevated hepatic enzymes, BUN, SrCr, and amylase, hyperkalemia, proteinuria, and prolonged bleeding time. May cause fetal harm; avoid use during pregnancy, especially in the 3rd trimester. Avoid with severe renal failure (GFR

<10mL/min), or with severe hepatic insufficiency. May increase protein-bound iodine result. Avoid use 1 week prior to and during labor and delivery.

ADVERSE REACTIONS

Respiratory depression, apnea, respiratory arrest, circulatory depression, hypotension, shock, lightheadedness, dizziness, drowsiness, sedation, N/V.

DRUG INTERACTIONS

ASA: May increase concentrations of acetazolamide, leading to toxicity. May diminish effects of ACE inhibitors, β-blockers, and diuretics. Bleeding risk increased with anticoagulants (eg, warfarin, heparin) and chronic, heavy alcohol use. May decrease total concentration of phenytoin and increase serum valproic acid levels. May enhance serious side effects and toxicity of methotrexate and ketorolac. Avoid with NSAIDs; may increase bleeding or lead to decreased renal function. May increase serum glucose-lowering action of insulin and sulfonylureas, leading to hypoglycemia. Antagonizes uricosuric action of probenecid or sulfinpyrazone. Oxycodone: May enhance neuromuscular-blocking action of skeletal muscle relaxants and increase respiratory depression. Additive CNS depression with opioid analgesics, general anesthetics, centrally acting antiemetics, phenothiazines, tranquilizers, sedative-hypnotics, or other CNS depressants (eg, alcohol); reduce dose of one or both agents. May cause severe hypotension with drugs that compromise vasomotor tone (eg, phenothiazines). Mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, naltrexone, butorphanol) may reduce analgesic effect and/or may precipitate withdrawal symptoms. Increased concentrations with CYP3A4 inhibitors (eg, macrolides, azole antifungals, protease inhibitors). Decreased concentrations with CYP450 inducers (eg, rifampin, carbamazepine, phenytoin).

PREGNANCY AND LACTATION

Category B (oxycodone) and D (ASA), not for use in nursing.

MECHANISM OF ACTION

ASA: NSAID; inhibits prostaglandin production, including those involved in inflammation. In CNS, works on hypothalamus heat-regulating center to reduce fever. Oxycodone: Opioid analgesic; pure opioid agonist. Principal therapeutic action is analgesia. Effects are mediated by receptors (notably μ and kappa) in the CNS for endogenous opioid-like compounds (eg, endorphins, enkephalins).

PHARMACOKINETICS

Absorption: ASA: Rapid from the stomach. Oxycodone: Absolute bioavailability (87%). **Distribution:** Found in breast milk; crosses placenta. Oxycodone: V_d=211.9L (IV); plasma protein binding (45%). **Metabolism:** ASA: Liver by microsomal enzymes; hydrolysis to salicylate. Oxycodone: Extensive by CYP3A4-mediated N-demethylation to noroxycodone (major); further oxidation to noroxymorphone (active). **Elimination:** ASA: Urine (80-100%; 10%, unchanged salicylate); $T_{1/2}$=15 min (ASA), 2-3 hrs (salicylate). Oxycodone: Urine (8-14%, unchanged); $T_{1/2}$=3.51 hrs.

ASSESSMENT

Assess for degree of opioid tolerance, level of pain intensity, type of pain, patient's general condition and medical status, any other conditions where treatment is contraindicated or cautioned, renal/hepatic function, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for signs/symptoms of respiratory depression, elevations in CSF pressure, hypotension, seizures/convulsions, decreased bowel motility in postoperative patients, spasm of sphincter of Oddi, GI ulceration and/or bleeding, physical dependence, tolerance, abuse/addiction, and other adverse reactions. Monitor platelet/renal/hepatic function.

PATIENT COUNSELING

Instruct to dispose of unused tabs by flushing down the toilet. Instruct not to adjust dose without consulting physician. Advise that drug may impair mental and/or physical abilities. Instruct to avoid alcohol or other CNS depressants. Advise to consult physician if pregnant, planning to become pregnant, or nursing. Inform that if taking medication for more than a few weeks, to avoid abrupt withdrawal; advise that dosing will need to be tapered. Inform that drug has potential for abuse, to protect it from theft, and not to give to anyone. Advise that drug may cause or worsen constipation; instruct to notify physician for any past history of constipation.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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