naltrexone (oral) (nal-trex-one)

naltrexone (injection)

Vivitrol

Classification
Therapeutic: alcohol abuse therapy adjuncts
Pharmacologic: opioid antagonists

Pregnancy Category C

Indications

Action
Competitively blocks the effects of opioids, including CNS and respiratory depression, without producing any agonist (opioid-like) effects. Mechanism in managing alcohol dependence may involve the endogenous opioid system. Therapeutic Effects: blocks the effects of opioids in previously dependent patients. Reduced alcohol-dependent behavior.

Pharmacokinetics
Absorption: Well absorbed orally, but undergoes extensive first pass hepatic metabolism resulting in 5–40% bioavailability. Well absorbed following IM administration.
Distribution: Enters breast milk.
Metabolism and Excretion: Extensively metabolized by the liver. Major metabolite (6-β-naltrexol) has opioid antagonist activity. Metabolites are excreted in urine.
Half-life: Oral: Naltrexone—4 hr; 6-β-naltrexol—15 hr; IM: Naltrexone—5–10 days; 6-β-naltrexol—5–10 days.

CONTRAINDICATIONS/Precautions
Contraindicated in: Hypersensitivity; Concurrent use of opioid analgesics or physiologic opioid dependence; Acute opioid withdrawal; Positive urine screen for opioids; Failed 6-β-naltrexol challenge test.
Use Cautiously in: History of hepatic impairment/damage; Moderate to severe renal impairment; History of depression or suicidal behavior/attempt; OB: Use only if maternal benefit outweighs fetal risk; Lactation, Pedi: Safety not established.

Adverse Reactions/Side Effects
CNS: SUICIDAL IDEATION, anxiety, fatigue, headache, insomnia, nervousness, depression, dizziness, q-energy, sedation.
EENT: hoarseness, runny/stuffy nose, sinus problems, sneezing.
Resp: EOSINOPHILIC PNEUMONIA (INJECTION), cough.
CV: palpitations.
GI: HEPATOTOXICITY, abdominal cramps/pain, nausea, constipation, appetite, diarrhea, vomiting.
GU: delayed ejaculation, erectile dysfunction.
Hemat: eosinophilia, thrombocytopenia.
Derm: skin rash.
Local: injection site reactions.
MS: muscle/joint pain.
Misc: chills, thirst.

Interactions
Drug-Drug: Concurrent use with thioridazine may q-CNS depression. May prevent therapeutic effects of opioid analgesics, antidiarrheals, and antitussives.

Route/Dosage
Opioid dependence
PO (Adults): Following a negative naloxone challenge and 7–10 days of opioid abstinence (longer for methadone), initial dose is 25 mg. If opioid withdrawal does not occur within 1 hr, additional 25 may be given. Maintenance dose is 50 mg daily as a single dose or 50 mg once daily on weekdays and 100 mg on Saturday or 100 mg
every other day or 150 mg every third day or 100 mg on Monday and Wednesday and 150 mg on Friday.

IM (Adults): 380 mg every 4 wk or once monthly.

Alcohol dependence

PO (Adults): 50 mg daily as a single dose or 50 mg every other day on weekdays and 100 mg on Saturday or 100 mg every third day or 100 mg on Monday and Wednesday and 150 mg on Friday.

IM (Adults): 380 mg every 4 wk or once monthly.

NURSING IMPLICATIONS

Assessment

- Assess patient for last time opioids or alcohol were taken. Patient must be free from opioids for 7–10 days prior to initiation of therapy. Naltrexone does not eliminate withdrawal symptoms (anxiety, shakiness, trembling, restlessness, nausea and vomiting, diarrhea, sweating, sleeplessness, muscle cramps). If physical dependence on opioids is possible, a Naloxone Challenge Test should be used. Patients transitioning from buprenorphine, buprenorphine/naloxone, or methadone are also at risk for developing withdrawal symptoms.
- Monitor closely for changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.
- Assess for signs of eosinophilic pneumonia (dyspnea, hypoxia, coughing, wheezing). Advise patient to seek treatment immediately if these symptoms occur.
- Lab Test Considerations: May cause liver enzymes, eosinophils, and platelet counts.

Potential Nursing Diagnoses

Ineffective coping (Indications)

Implementation

- Naltrexone should be used in conjunction with a comprehensive alcohol or drug program. Patient should not be actively drinking at the time of naltrexone initiation.
- If emergent analgesia is required for pain management, regional analgesia, conscious sedation with a benzodiazepine, and use of non-opioid analgesics or general anesthesia are recommended. If opioid analgesics are required, the amount may be greater than usual and the respiratory depression deeper and more prolonged. A rapidly acting opioid that minimizes the duration of respiratory depression is recommended.
- IM: Must be administered by a health care professional every 4 wk or once a month. Remember using only a diluent and needle supplied. A spare administration needle is provided in case of clogging. Do not substitute other components. Allow drug to reach room temperature, approximately 3 h, before preparing. To ease mixing, firmly tap needle on a hard surface, ensuring powder moves freely. Using the 1/2 inch preparation needle, withdraw 3–4 mL of clear diluent and mix into microsphere vial. Mix by shaking vigorously for approximately 1 min. Suspension is milky white without clumps and moving freely up and down the wall of the vial. Immediately after suspension, withdraw 0.2 mL of suspension using same preparation needle. Remove preparation needle and replace with 1/2 or 2 inch administration needle for immediate use. Prior to administration, tap syringe to remove any bubbles, then gently push plunger until 0.2 mL of suspension remains in syringe. Activate safety sheath by pressing against hard surface in lower needle. Store in refrigerator, do not freeze; may be kept at room temperature for 7 days.
- Administer IM into the gluteal muscle using pre-packaged 1 1/2- or 2-inch needle specifically designed for this drug. Should all needles or administration to fatty tissue.
- If a dose is missed, patient should receive dose as soon as possible.

Patient/Family Teaching

- Instruct patient to take naltrexone as directed. Inform patients that there are potentially serious consequences and possible death if they try to overcome the effects of opioids with higher doses of opioids.
- Warn patient to avoid driving and other activities requiring alertness until effects of the medication are known.
- Encourage patient and family to be alert for emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, elation, delirium, and/or dizziness or other symptoms on a day-to-day basis or changes may be abrupt. If these symptoms occur, notify health care professional.
CONTINUED

naltrexone (injection)

- Inform patient of the risk of hepatic injury. Advise patient to notify health care professional if signs of acute hepatitis (abdominal pain lasting more than a few days, white bowel movements, dark urine, or yellowing of eyes) occur; naltrexone should be discontinued.
- Advise patient and family that they may be more sensitive to lower doses of opioids after naltrexone treatment ends. When next dose is due, and if a dose is missed, advise patients that they will not perceive any effects from small doses of opioids and may not experience the same effects from opioid containing analgesics, antiarrhythmics, or antidepressants. This can lead to overdose including respiratory arrest, coma, or death.
- Advise patient to notify health care professional if pregnancy is planned or suspected.
- Advise patient to carry identification to alert medical personnel of naltrexone therapy.
- IM: May cause injection site reactions (cellulitis, induration, hematoma, abscess, sterile abscess, necrosis). Advise patient to monitor injection site and notify health care professional if pain, swelling, tenderness, induration, bruising, pruritus, or redness at the injection site occurs and does not improve or worsens within 2 wk. Promptly refer patients with worsening injection site reactions to a surgeon.

Evaluation/Desired Outcomes
- The blockade of the effects of exogenously administered opioids.
- Management of alcoholism.

Why was this drug prescribed for your patient?