

ATTACHMENT 3

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USP DI(R) Drug Information for the Health Care Professional

Opioid (Narcotic) Analgesics (Systemic)

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This monograph includes information on the following:

- 1) Anileridine *
- 2) Butorphanol †
- 3) Codeine
- 4) Hydrocodone[±] *
- 5) Hydromorphone
- 6) Levorphanol
- 7) Meperidine
- 8) Methadone
- 9) Morphine
- 10) Nalbuphine
- 11) Opium
- 12) Oxycodone
- 13) Oxymorphone
- 14) Pentazocine
- 15) Propoxyphene

Note: See also individual [Buprenorphine \(Systemic\)](#) and [Dezocine \(Systemic\)](#) monographs.
See also [Fentanyl Derivatives \(Systemic\)](#) for information on alfentanil, fentanyl, and sufentanil.

INN:

Meperidine —Pethidine

Propoxyphene—Dextropropoxyphene

VA CLASSIFICATION**Anileridine****Primary:** CN101**Secondary:** CN206**Butorphanol**

Pregnancy/Reproduction

Pregnancy—

Risk-benefit must be considered because opioid analgesics cross the placenta. Regular use during pregnancy may cause physical dependence in the fetus, leading to withdrawal symptoms (convulsions, irritability, excessive crying, tremors, hyperactive reflexes, fever, vomiting, diarrhea, sneezing, and yawning) in the neonate. Use of methadone by pregnant women participating in methadone maintenance programs has also been associated with fetal distress *in utero* and low birth weight.

For butorphanol, nalbuphine, pentazocine, and propoxyphene: Although studies in humans have not been done, studies in animals have not shown that these agents cause adverse effects on fetal development (Pentazocine and naloxone tablets—FDA Pregnancy Category C).

For codeine, hydrocodone, hydromorphone, morphine, and opium: Although teratogenic effects in humans have not been documented, controlled studies have not been done. Studies in animals have shown codeine (single dose of 100 mg per kg) to cause delayed ossification in mice and (in doses of 120 mg per kg) increased resorptions in rats, and hydrocodone, hydromorphone, and morphine to be teratogenic in very high doses (FDA Pregnancy Category C).

For anileridine, levorphanol, meperidine, methadone, oxycodone, and oxymorphone: Although teratogenic effects in humans have not been documented, controlled studies have not been done^[90].

Labor and delivery—

Opioid analgesics, including epidurally or intrathecally administered opioids, readily enter the fetal circulation when used during labor and may cause respiratory depression in the neonate, especially the premature neonate. These agents should be used with caution, if at all, during the delivery of a premature infant. Methadone is not recommended for obstetrical analgesia because its long duration of action increases the risk of neonatal respiratory depression. Also, morphine, hydromorphone, codeine, and possibly other opioids may prolong labor. Intrathecal administration of up to 1 mg of morphine sulfate has little effect on the first stage of labor but may prolong the second stage of labor.

Breast-feeding

Problems in humans with most opioid analgesics have not been documented. Butorphanol, codeine, meperidine, methadone, morphine, and propoxyphene are distributed into breast milk. Information concerning the distribution of other opioid analgesics into breast milk is lacking. With usual analgesic doses, concentrations of those drugs known to be distributed into breast milk are generally low. However, risk-benefit must be considered when methadone is administered to a nursing mother in a methadone maintenance program because use of maintenance doses may cause physical dependence in the infant.

Pediatrics

Children up to 2 years of age may be more susceptible to the effects, especially the respiratory depressant effects, of these medications.

Paradoxical excitation is especially likely to occur in pediatric patients receiving opioid analgesics.

Geriatrics

Geriatric patients may be more susceptible to the effects, especially the respiratory depressant effects, of these medications. Also, geriatric patients are more likely to have prostatic hypertrophy or obstruction and age-related renal function impairment, and are therefore more likely to be adversely affected by opioid-induced urinary retention. In addition, geriatric patients may metabolize or eliminate these medications more slowly than younger adults. Lower doses or longer dosing intervals than those usually recommended for adults may be required, and are usually therapeutically effective, for these patients.

Dental

Opioid analgesics may decrease or inhibit salivary flow, thus contributing to the development of caries, periodontal disease, oral candidiasis, and discomfort.