HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BUTRANS® safely and effectively. See full prescribing information for BUTRANS.

BUTRANS (buprenorphine) Transdermal System for transdermal administration CIII
Initial U.S. Approval: 1981

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

See full prescribing information for complete boxed warning.

- **BUTRANS contains buprenorphine, a Schedule III controlled substance. Monitor for signs of misuse, abuse, and addiction during BUTRANS therapy (5.1, 9).**
- **Fatal respiratory depression may occur, with highest risk at initiation and with dose increases. Instruct patients on proper administration of BUTRANS to reduce the risk (5.2).**
- **Accidental exposure to BUTRANS can result in fatal overdose of buprenorphine, especially in children (5.3).**

----------RECENT MAJOR CHANGES----------

Boxed Warning	07/2012
Indications and Usage (1)	07/2012
Dosage and Administration (2)	07/2012
Contraindications (4)	07/2012
Warnings and Precautions (5)	07/2012

----------INDICATIONS AND USAGE----------

BUTRANS is a partial opioid agonist product indicated for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. (1)

Limitations of Use

- BUTRANS is not for use:
  - As an as-needed (prn) analgesic (1)
  - For pain that is mild or not expected to persist for an extended period of time (1)
  - For acute pain (1)
  - For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time (1)

----------DOSAGE AND ADMINISTRATION----------

- Individualize dosing based on patient's prior analgesic treatment experience, and titrate as needed to provide adequate analgesia and minimize adverse reactions. (2.1, 2.2)
- Instruct patients to wear BUTRANS for 7 days and to wait a minimum of 3 weeks before applying to the same site. (2.1)
- Do not abruptly discontinue BUTRANS in a physically dependent patient. (2.3, 5.17)

----------DOSAGE FORMS AND STRENGTHS----------

- **Transdermal system**, 5 mcg/hour, 10 mcg/hour, and 20 mcg/hour. (3)

----------CONTRAINDICATIONS----------

- Significant respiratory depression (4)
- Acute or severe bronchial asthma (4)
- Known or suspected paralytic ileus (4)
- Hypersensitivity to buprenorphine (4)

----------WARNINGS AND PRECAUTIONS----------

- Elderly, cachectic, and debilitated patients, and patients with chronic pulmonary disease: Monitor closely because of increased risk of respiratory depression. (5.4, 5.5)
- Interaction with CNS depressants, especially benzodiazepines: Consider dose reduction of one or both drugs because of additive effects. (5.6, 7.2, 7.3)
- Avoid in patients with Long QT Syndrome, family history of Long QT Syndrome, or those taking Class IA or Class III antiarrhythmic medications. (5.7, 12.2)
- Hypotensive effects: Monitor during dose initiation and titration. (5.8)
- Patients with head injury or increased intracranial pressure: Monitor for sedation and respiratory depression and avoid use of BUTRANS in patients with impaired consciousness or coma susceptible to intracranial effects of CO_2 retention. (5.9)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥ 5%) include: nausea, headache, application site pruritus, dizziness, constipation, somnolence, vomiting, application site erythema, dry mouth, and application site rash. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Purdue Pharma L.P. at 1-888-726-7535 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

- CYP3A4 inducers: May increase clearance of buprenorphine. (7.1)
- Interaction with CNS depressants: Consider dose reduction of one or both drugs because of additive effects. (5.6, 7.3)
- Muscle relaxants may enhance the action of BUTRANS and produce an increased degree of respiratory depression. (7.4)

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: BUTRANS is not recommended for use during pregnancy. (8.1)
- Nursing Mothers: Buprenorphine has been detected in human milk. Closely monitor infants of nursing women receiving BUTRANS. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 07/2012