Brandogesic® (muenkephalin)

Prescribing Information

INDICATION

Brandogesic® is indicated for the management of moderate to severe chronic pain when analgesia is needed for an extended period of time.

CONTRAINDICATIONS

Brandogesic® is contraindicated in patients with a known hypersensitivity to muenkephalin or any of the ingredients of Brandogesic®.

Brandogesic® is contraindicated in patients with respiratory depression (unless monitored in a setting with resuscitative equipment), asthma, head injury or ileus.

Brandogesic® is not indicated for pain in the pre- or post-operative period.

WARNINGS

Respiratory depression that does not respond to hypercapnia is the most significant risk associated with Brandogesic®. Brandogesic® should be administered cautiously to patients with conditions accompanied by hypercapnia, hypoxia or impaired respiratory reserve.

Many medications, including alcohol, other analgesics or anesthetics, tranquilizers and sedatives, or other CNS depressants can potentiate the effects of Brandogesic®, resulting in respiratory or circulatory collapse, coma or death.

In the presence of closed head injury, the hypercapnic effects of Brandogesic® may elevate intracranial pressure.

Brandogesic® may exacerbate gastrointestinal obstruction, particularly in the setting of ileus.

Brandogesic® may cause spasm at the Sphincter of Oddi.

Brandogesic® is not recommended for women who are or may become pregnant, during labor and delivery, or while nursing.

Patients should not perform activities such as driving a car or operating machinery until they understand the effects of Brandogesic® on mental and physical abilities.

ADVERSE REACTIONS

Adverse reactions reported at (≥5%) in placebo-controlled trials were: sedation and somnolence or insomnia, nausea and/or vomiting, constipation or diarrhea, dizziness, pruritus and headache.

Dizziness, somnolence and confusion were seen more frequently in patients 65 years of age and over.