

## Long-Term Use of Buprenorphine Transdermal System (BTDS) in Patients with Chronic Pain

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### Purpose

To evaluate the long-term use of BTDS, a 7-day matrix transdermal system containing buprenorphine, a mu opioid partial agonist, in patients with chronic pain.

### Method

Patients with primarily low back pain or osteoarthritis pain were enrolled into the respective open-label BTDS extension from 10 double-blind randomized studies in which they had received either BTDS, oxycodone/acetaminophen, immediate-release oxycodone, or placebo. Patients began on BTDS 5 (5 mcg/hour) applied every 7 days and titrated to BTDS 10 (10 mcg/hour) or BTDS 20 (20 mcg/hour), if necessary, for effective analgesia. Non-study supplied rescue medications (short-acting opioids and NSAIDs) were allowed in the extension for pain rescue. The disposition, exposure, and adverse event profile were evaluated using the pooled data from this population. One of the extension studies (which enrolled patients from 3 double-blind studies) evaluated long-term maintenance of analgesia (ie, pain scores), impact on functions, QoL, and health outcomes.

### Results

The mean age of the pooled extension population (N=1576) was 57 years (range, 22-98), with 31% of the patients aged  $\geq 65$  and 10% aged  $\geq 75$ , 62% female, 91% white. The mean BTDS exposure was 162 days (range 1-610). 1127, 728, and 154 patients were treated with BTDS for at least 3 months, 6 months, and 12 months, respectively. 24% discontinued due to AE and 7% discontinued due to lack of therapeutic effect during the extension studies.

**Safety:** The most common adverse events (occurring in  $\geq 5\%$  patients) were nausea, constipation, vomiting, application site erythema, application site pruritus, application site rash, back pain, arthralgia, pain in extremity, headache, dizziness, and somnolence.

**Efficacy:** In the extension study that evaluated long-term maintenance of analgesia (N=384), the screening mean "pain on average" was 6.7 (0- 10 NRS). The pain scores improved with treatment and remained constant (range: 4.6 to 4.9 from month 2 through month 12 of the extension), consistent with long-term analgesic benefit. Modest improvements in functionality, QoL, and health outcomes were maintained.

### Conclusions

Results of the long-term studies showed that BTDS was well-tolerated for most patients and, in the 1 study where the pain was assessed, adequate pain control was maintained.