



Fentora[®] (fentanyl) – First-time generic (authorized generic)

- On June 13, 2019, Mayne Pharmaceuticals launched an authorized generic version of Teva's [Fentora \(fentanyl\)](#) buccal tablets.
 - Fentora is a scheduled II controlled substance.
- Fentora is approved for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.
- Fentanyl is also available generically as an [injection](#), oral transmucosal [lozenge](#), and [transdermal system](#); and as brand sublingual tablet ([Abstral[®]](#)), an iontophoretic transdermal system ([lonsys[®]](#)), nasal spray ([Lazanda[™]](#)), and a sublingual spray ([Subsys[®]](#)).
 - The injection is indicated as an analgesic prior to, during, and after anesthesia.
 - The lozenge, Abstral, Lazanda, and Subsys carry the same indication as Fentora except the lozenge is approved for patients 16 years of age and older.
 - The transdermal system is for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
 - lonsys is indicated for the short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate.
- Fentora carries a boxed warning for life-threatening respiratory depression; accidental ingestion; risks from cytochrome P450 3A4 interaction; risks from concomitant use with benzodiazepines or other central nervous system depressants; risk of medication errors; addiction, abuse, and misuse; risk evaluation and mitigation strategy; and neonatal opioid withdrawal syndrome.



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