



FDA News Release

FDA approves labeling with abuse-deterrent features for third extended-release opioid analgesic

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For Immediate Release

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Release

The U.S. Food and Drug Administration today approved new labeling for Embeda (morphine sulfate and naltrexone hydrochloride) extended-release (ER) capsules, an opioid analgesic to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Embeda is the third ER opioid analgesic to be approved with labeling describing the product's abuse-deterrent properties consistent with the FDA's 2013 draft guidance, [Abuse-Deterrent Opioids – Evaluation and Labeling](#). The new labeling includes a claim indicating that Embeda has properties that are expected to reduce oral abuse when the product is crushed.

Embeda has properties that are expected to reduce, but not totally prevent, abuse of the drug when crushed and taken orally or snorted. Embeda works by releasing only the morphine in the capsule when taken properly. When crushed, the naltrexone in Embeda blocks some of the euphoric effects of the morphine and can precipitate withdrawal in persons dependent on opioids.

When swallowed intact, however, Embeda can still be abused or misused because the naltrexone is not expected to substantially block the euphoric effects of the morphine. It is unknown whether the abuse-deterrent properties of Embeda will result in a reduction in abuse by the intravenous route until additional postmarketing data

are available.

Embeda can still be abused or misused by any of these routes, and such abuse or misuse can cause an overdose that may result in death. If abused, it can also cause withdrawal in people who are dependent on, or tolerant to, opioids.

"Preventing prescription opioid abuse and ensuring that patients have access to appropriate treatments for pain are both top public health priorities for the FDA," said Sharon Hertz, M.D., acting director of the Division of Anesthesia, Analgesia, and Addiction Products in the FDA's Center for Drug Evaluation and Research. "The science behind developing prescription opioids with abuse-deterrent properties is still evolving and these properties will not completely fix the problem. But they can be part of a comprehensive approach to combat the very serious problem of prescription drug abuse in the U.S."

Embeda is not approved, and should not be used, for as-needed pain relief. Given Embeda's risks for abuse, misuse, and addiction, it should only be prescribed to people for whom alternative treatment options are ineffective, not tolerated or would be otherwise inadequate to provide sufficient pain management.

Embeda was first approved on August 13, 2009, but was voluntarily withdrawn from the market in March 2011, due to testing that found stability concerns in the manufacturing process. The FDA confirmed that these issues were resolved with its approval of a manufacturing supplement in November 2013.

When Embeda was first approved, the drug was evaluated in a clinical trial of 547 osteoarthritis patients. Additional data from abuse liability studies conducted in laboratories and in people demonstrated the abuse-deterrent features of Embeda for certain types of abuse (oral and snorting), when the product was crushed. The abuse potential for the intravenous route was studied by simulating the amount of morphine and naltrexone that would be released upon crushing Embeda. This study demonstrated that Embeda was less attractive to abusers or less likely to produce a high (lower "Drug Liking" and "Drug High") compared with morphine alone. However, it is unknown whether these results with simulated crushed Embeda predict a reduction in abuse by the intravenous route until additional postmarketing data are available.

The FDA is requiring postmarketing studies of Embeda to further assess the effects of the abuse-deterrent features on the risk for abuse of Embeda and the consequences of that abuse. In addition, Embeda is part of the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS), which requires companies to make available to health care professionals educational programs on how to safely prescribe ER/LA opioid analgesics and to provide Medication Guides and patient counseling documents containing information on the safe use, storage, and disposal of ER/LA opioids.

Embeda is marketed by New York City-based Pfizer, Inc.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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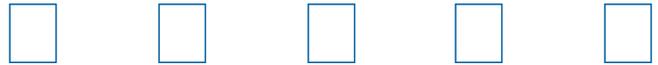
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