

Pain Medication Embeda Is Recalled From The Market

On March 15th, 2011 King Pharmaceuticals, Inc. voluntarily recalled all dosages of its combination morphine sulfate and naltrexone hydrochloride prescription drug, Embeda (**Embeda Extended Release Capsules CII**), from wholesalers and retailers in the United States. According to the product's website, the reason for this recall is "a pre-specified stability requirement was not met during routine testing". King Pharmaceuticals, a wholly owned subsidiary of Pfizer, has apologized for any inconvenience this recall may cause. ¹

Available data suggest that the issue is unlikely to pose a safety risk to patients using Embeda as prescribed. Pfizer notes that patients can continue taking the product as prescribed, and should not stop taking it without consulting their physician about switching to another opioid. They are advised to explore alternate forms of pain relief with their healthcare provider before coming to the end of their current supply. ¹

According to Chip Robison, Pharm.D., chairman of the Cypress Care's pharmacy and therapeutics (P&T) committee, "Cypress Care has reviewed the safety and effectiveness of Embeda. We view this recent recall as a quality control issue. King Pharmaceuticals evidently did not complete the proper stability studies prior to release of certain lots of Embeda, but has now taken steps to ensure the drug is recalled."

"The FDA has strict requirements on the testing of drug stability to avoid their premature decomposition and loss of potency", Robison added. "We consider this voluntary recall to be primarily a supply issue that will likely inconvenience our network pharmacies. At this time, Embeda will continue to be recommended to our clients as a workers' compensation formulary drug with the ability to deter abuse. We have been in contact with Pfizer, but no re-stock date has been communicated for Embeda. In many cases, this will necessitate the physician needing to prescribe an alternative pain medication."

If you have questions about this recall, please call Pfizer's medical information line at 800.776.3637.



Chip Robison, Pharm.D.
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Reference

¹2011. Important Information for Patients and Prescribers. Embeda. Retrieved March 16, 2011 from <http://www.embeda.com/>