

Embeda[®] Voluntary Recall

(Morphine Sulfate and Naltrexone Hydrochloride)

IMPORTANT NOTICE

On March 15, 2011, King Pharmaceuticals announced a voluntary recall of all dosages of Embeda, a combination product containing morphine sulfate and naltrexone hydrochloride. Although detailed information regarding the recall has yet to be provided by the manufacturer, King Pharmaceuticals indicates that pre-specified stability requirements were not met during routine testing of the product. This resulted in a voluntary recall at the wholesaler and pharmacy level—a patient level recall has not been initiated.

BACKGROUND

Embeda was approved in August 2009 for the treatment of moderate to severe pain in patients requiring continuous, around-the-clock pain relief. Unlike other morphine formulations, Embeda contains naltrexone, an opioid antagonist intended to help curb inappropriate use of the medication, which could occur by crushing or chewing of the dosage form.

Since its approval, Embeda has experienced several setbacks in its market lifecycle. Shortly after approval, the FDA indicated it had concerns regarding the drug's marketing campaign, citing that the manufacturer had provided information that minimized the risks associated with Embeda, failed to disclose the limitations to the analgesic's approved indication, and provided misleading claims. Later in March and April 2010, certain lots of Embeda were voluntarily recalled due to issues identified with the product's dissolution, as revealed through standard post-manufacturing tests.

RECOMMENDED ACTIONS

King Pharmaceuticals

At this time, the FDA has not issued a formal recall for Embeda; King Pharmaceuticals has voluntarily recalled this product from the market. Currently, King Pharmaceuticals indicates that the identified issue is unlikely to pose a safety risk to patients using Embeda as prescribed. Patients are urged not to stop taking Embeda without first consulting with their physician about switching to alternative agents. More information regarding the recall can be obtained by directly contacting King Pharmaceuticals at 1-800-776-3637.

PMSI Actions

PMSI has identified a total of 310 injured workers who have received Embeda within the last 90 days accounting for 0.4% of total drug spend, and will alert their respective prescribers regarding this voluntary recall.



Patient Actions

Due to the controlled, Schedule II status of this agent, patients are required to contact their prescriber to obtain a new prescription for a replacement product. Patients should continue to utilize their existing supply of Embeda as prescribed and contact their prescriber regarding alternative agents before their current supply runs out.

ALTERNATIVE PRODUCTS

The following products have been identified as potential alternatives for patients requiring continued long-acting analgesics. For comparison purposes, the average cost per day of supply for Embeda is \$17.39.

Alternative Agents	Average Cost per Day of Supply
Avinza® (no generic available)	\$12.61
Kadian® (no generic available)	\$28.81
Morphine SR (generic formulation)	\$9.12
OxyContin® (no generic available)	\$17.70

CONCLUSION

This PMSI Drug Advisory is made available by our clinical pharmacist team to provide you pertinent drug information and identify the potential impact on your injured workers’ care and your costs. As your pharmacy partner, PMSI understands the importance of staying on top of breaking news in the pain management arena and keeping you informed. We will continue to monitor and regularly communicate our proactive response to FDA recommendations to help protect your interests.

DISCLAIMER

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REFERENCES

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