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### FOR IMMEDIATE RELEASE

# **UPSHER-SMITH LAUNCHES MORPHINE SULFATE TABLETS**

Maple Grove, MN – August 27, 2019 – Upsher-Smith Laboratories, LLC (Upsher-Smith) today announced the launch of Morphine Sulfate Tablets, CII, 15 and 30 mg.

The morphine sulfate tablet market had U.S. sales of approximately \$49 million for the 12 months ending June 2019 according to IQVIA.

### **Upsher-Smith Product Information**

Product	Strength	NDC #	Package Size
Morphine Sulfate Tablets, CII	15 mg	0832-0273-11	100 ct
Morphine Sulfate Tablets, CII	30 mg	0832-0274-11	100 ct

For questions about ordering, please call Upsher-Smith at 1-800-654-2299.

WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

See full prescribing information for complete boxed warning.

- Morphine sulfate tablets expose users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions. (5.1)
- To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for these products. (5.2)
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. (5.3)
- Accidental ingestion of morphine sulfate tablets, especially by children, can result in a fatal overdose of morphine. (5.3)
- Prolonged use of morphine sulfate tablets during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.4)
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation. (5.5, 7)

Please refer to the full Prescribing Information, including Boxed Warning for Morphine Sulfate Tablets, CII here. You can also call 1-888-650-3789 to obtain a copy of the full Prescribing Information.

You are encouraged to report suspected adverse reactions to Upsher-Smith Laboratories, LLC at 1-855-899-9180 or to the FDA by visiting http://www.fda.gov/medwatch.

## About Upsher-Smith

Upsher-Smith Laboratories, LLC is a trusted U.S. pharmaceutical company that strives to improve the health and lives of patients through an unwavering commitment to high-quality products and sustainable growth. Since 1919, it has brought generics and brands to a wide array of customers backed by an attentive level of service, strong industry relationships, and dedication to uninterrupted supply.

As Upsher-Smith celebrates its 100-year anniversary, the company enters a new ambitious era that has been accelerated by its 2017 acquisition by Sawai Pharmaceutical Co., Ltd. Upsher-Smith and Sawai plan to leverage each other for growth worldwide and embark on an exciting new chapter as they seek to deliver the best value for their stakeholders, and most importantly, Do More Good<sup>™</sup> for the patients they serve. For more information, visit www.upsher-smith.com.

Do More Good is a trademark of Upsher-Smith Laboratories, LLC.

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