Eisai Co., Ltd.

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Eisai is a Human Health Care Corporation striving for innovative solutions in prevention, cure and care for the health and well-being of people worldwide. We combine our talents to understand and meet the needs of patients and their families to enhance the quality of life.

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Eisai Co., Ltd.

Eisai Launches Sedative-Hypnotic Agent LUSEDRA™ Injection CIV in the United States

Eisai Inc. (Headquarters: New Jersey, the United States, President and CEO: Hajime Shimizu), a U.S. subsidiary of Eisai Co., Ltd. (Headquart

LUSEDRA is a proprietary water-soluble prodrug of propofol that, after intravenous injection, is converted by alkaline phosphatase enzymes in the body into propofol prior to exerting sedative effects.

The U.S. Food and Drug Administration (FDA) approved LUSEDRA in December 2008 for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures. The agent is designated as a Schedule IV controlled substance.

With the launch of LUSEDRA, Eisai is able to provide a new option for sedation for patients undergoing diagnostic or therapeutic procedures and remains committed to making further contributions to addressing the diversified needs and increasing the benefits of patients and healthcare professionals.

[Please refer to the following notes for the U.S. product outline]

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<Notes to editors>

Â **U.S. Product Outline of LUSEDRA™**

Product Name:

LUSEDRA™ Injection CIV

Generic Name:

fospropofol disodium

Formulation:

Injection solution for intravenous administration

Indication and Usage:

LUSEDRA is indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures.

Dosage and Administration:

- Standard Dosing Regimen:
  - ü In adults aged 18 to <65 years who are healthy or have mild systemic disease (ASA P1 or P2), the standard dosing regimen of LUSEDRA is an initial intravenous bolus of 6.5 mg/kg followed by supplemental doses of 1.6 mg/kg intravenously (25% of initial dosage) as needed to achieve the desired level of sedation.
- Modified Dosing Regimen:
  - ü In adults 65 years of age or those with severe systemic disease (APA P3 or P4) should receive initial and supplemental intravenous dosages of 75% of the standard dosing regimen.

Please refer to full prescribing information for complete dosing and safety information.

Warnings and Precautions:

LUSEDRA should be administered only by persons trained in the administration of general anaesthesia and not involved in the conduct of the diagnostic or therapeutic procedure. Sedated patients should be continuously monitored, and facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation must be immediately available. Patients should be continuously monitored during sedation and through the recovery process for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.

Adverse Reactions:

Serious adverse reactions such as apnea, hypoxemia, loss of purposeful responsiveness, or hypotension were reported in patients treated with LUSEDRA. The most common adverse reactions reported in greater than 20% are paresthesia and pruritus.