

SEDANA MEDICAL RECEIVES AN ADDITIONAL YEAR OF MARKET PROTECTION FOR SEDAONDA® (ISOFLURANE)

Sedana Medical AB (publ) announces that Sedaonda® (isoflurane) has received an additional year of market protection, extending the protection period until 2032. The decision is based on the regulatory assessment that the recently approved paediatric extension of the Sedaonda indication brings a significant clinical benefit over existing therapies.

Sedana Medical announced on 13 December 2024 that the Type II variation to extend the indication of Sedaonda® (isoflurane) to include paediatric patients of 3-17 years had received a positive decision at the End of Procedure (EOP) from the Reference Member State (RMS) Germany and 12 Concerned Member States (CMS) in Europe. National approval processes are currently ongoing, with the new indication approved in 9 countries to date, including in Sedana Medical's biggest market, Germany.

The CMDh (Co-ordination Group for Mutual Recognition and Decentralized Procedures – Human) have now agreed by consensus to an additional year of market protection (to 2032). In their argumentation, CMDh stated:

“Currently, midazolam is the only authorised sedative for paediatric use in intensive care, hence, there is an unmet medical need for alternative treatments. Isoflurane at doses up to 1.0 Vol% has been shown to provide adequate sedation for paediatric invasively ventilated patients comparable to midazolam with less requirements for supplemental opioids. In addition, isoflurane is eliminated unchanged by exhalation via lungs, resulting in a faster and more predictable time to extubation. It can therefore be used without dose-reduction in patients with impaired renal or hepatic function, which is common in critically ill paediatric ICU patients. There was no evidence of short-term tolerance.

In conclusion, the new (expanded) indication represents a significant clinical benefit over existing therapies.”

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This information is information that Sedana Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-02-03 17:30 CET.

About Sedana Medical

Sedana Medical AB (publ) is a pioneer medtech and pharmaceutical company focused on inhaled sedation to improve the patient's life during and beyond sedation. Through the combined strengths of the medical device Sedaconda ACD and the pharmaceutical Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated patients in intensive care.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics, and Spain. In other parts of Europe as well as in Asia, Australia, Canada, and South- and Central America, the company works with external distributors.

Sedana Medical was founded in 2005, is listed on Nasdaq Stockholm (SEDANA) and headquartered in Stockholm, Sweden.

Attachments

Sedana Medical receives an additional year of market protection for Sedaconda® (isoflurane)