

Mallinckrodt's INOmax receives approval in Australia

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Expands approved indication in Australia to include use of INOmax for perioperative pulmonary hypertension in conjunction with cardiovascular surgery in neonates through adults



Mallinckrodt plc a leading global specialty pharmaceutical company has announced that INOmax™ (nitric oxide) gas, for inhalation has received regulatory approval in Australia by the Australian Therapeutic Goods Administration (TGA) for perioperative pulmonary hypertension in adults in conjunction with cardiovascular surgery.

INOmax was previously approved for this same indication in neonates through adolescents up to age 17, and is also approved in Australia for the treatment of hypoxic respiratory failure (HRF) associated with pulmonary hypertension, a potentially life-threatening condition, in term and near-term newborns (>34 weeks).

INOmax nitric oxide is a vasodilator that opens (dilates) blood vessels, improving oxygen uptake and blood flow. It is used in conjunction with ventilator support and other appropriate agents. INOmax decreases pulmonary arterial pressure.

"This expanded approval of INOmax in Australia for cardiovascular surgery in adults is an important milestone for Mallinckrodt, confirming the benefit this therapeutic option can bring to perioperative pulmonary hypertension patients," said Steven Romano, M.D., Executive Vice President and Chief Scientific Officer, Mallinckrodt. "We continue to focus on improving outcomes for underserved patients with severe and critical conditions, and this is an example of those efforts making a difference. There is a tremendous global need for therapies for patients undergoing cardiac surgery. We look forward to helping meet these needs."