VENTAVIS® (iloprost)
Product Status

SUMMARY

- VENTAVIS® (iloprost) is indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) to improve a composite endpoint consisting of exercise tolerance, symptoms (New York Heart Association [NYHA] Class), and lack of deterioration.[1]
- VENTAVIS is FDA-approved for administration only using the I-neb® AAD® System, which is manufactured by Philips Respironics.[1]
- On September 12, 2023, Johnson & Johnson was notified by Philips Respironics of its decision to discontinue the I-neb® AAD® system.[1]
- Because the I-neb® AAD® system is the only FDA-approved device for the administration of VENTAVIS, Johnson & Johnson has notified the FDA in 2024 that it would be delisting the VENTAVIS medication.[1]
- Because the I-neb® AAD® system is required for the administration of VENTAVIS, patients using this product will be impacted by its discontinuation. Healthcare providers should explore alternate treatments for patients using VENTAVIS.[1]

BACKGROUND

As of September 12, 2023, Philips Respironics has made the business decision to discontinue its I-neb® AAD® system. Because the I-neb AAD system is required for administration of VENTAVIS, Johnson & Johnson has made the decision to delist the medication. The discontinuation of the I-neb® AAD® system and the delisting of VENTAVIS are not due to any quality or safety issues, and they remain safe to use for patients currently on this medication.[1]

Johnson & Johnson stopped supplying VENTAVIS in March 2025. The medication is no longer sold.[1]

In the months since Philips Respironics announced its plan to discontinue the I-neb® AAD® system, Johnson & Johnson has proactively notified healthcare providers recommending that they explore alternate treatments for their patients. Those transitions are underway and should help minimize treatment disruptions.[1]

Healthcare providers should explore alternate treatments for patients utilizing VENTAVIS and refrain from initiating new patients on this medication.[1]

Because the I-neb® AAD® system is the only FDA-approved device for the administration of VENTAVIS, its discontinuation only impacts the U.S. market. VENTAVIS outside of the U.S. is not distributed by Johnson & Johnson, and therefore healthcare providers outside of the U.S. are encouraged to contact the distributor in their market for the most up-to-date information.[1]

REFERENCE

1. Data on File. VENTAVIS (iloprost) Inhalation Solution Delisting U.S. Message Map; 2024.