VELETRI® (epoprostenol)
VELETRI - Treatment of Acute Respiratory Distress Syndrome (ARDS)

SUMMARY

- Data regarding treatment of acute respiratory distress syndrome (ARDS) with intravenous (IV) epoprostenol is limited.[1,2]
- Data regarding treatment of ARDS with inhaled epoprostenol is limited to prospective, nonrandomized, interventional studies,[3-6] retrospective data analyses,[7-19] and case series or reports.[20-27]
- The risk-benefit ratio related to the administration of VELETRI for injection via inhalation has not been established. The dosage and method of administration of VELETRI for injection should be in accordance with that specified in the product label.

CLINICAL DATA

Use of IV Epoprostenol to Treat ARDS

There are limited reports in the medical scientific literature of the treatment of ARDS with IV epoprostenol consisting of case series or case reports.[1,2]

Use of Inhaled Epoprostenol to Treat ARDS

There are limited reports in the medical scientific literature of the treatment of ARDS with inhaled epoprostenol consisting of prospective, nonrandomized, interventional studies[3-6] and several retrospective data analyses,[7-19] case series, or case reports.[20-27] Studies have also been included in an article collection[28] and a systematic review.[29]

VELETRI pH and L-Arginine Content

It should be noted that the pH of the VELETRI for injection "ready-to-use solution" decreases with dilution, and ranges from 12.0 for a concentration of 90,000 ng/mL, 11.7 for a concentration of 45,000 ng/mL to 11.0 for a concentration of 3000 ng/mL.

Furthermore, compared to other epoprostenol diluted solutions, which are buffered with glycine (eg, Flolan®), VELETRI for injection contains L-arginine (50 mg per vial). Inhaled L-arginine has been investigated in patients with asthma[30-32] and cystic fibrosis,[33,34] sometimes alongside healthy subjects. Although subject exposure to inhaled L-arginine in these studies was larger than would be expected to occur with the administration of VELETRI for injection via inhalation, some of the studies reported inhaled L-arginine to be associated with an amplified inflammatory response in airways and an increased risk of bronchoconstriction.

Taken together, the higher pH and L-arginine content of VELETRI for injection have the theoretical potential to be the cause of adverse events when administered via inhalation. Overall, the risk-benefit ratio relating to the administration of VELETRI for injection via inhalation has not been established. The dosage and method of administration of VELETRI for injection should be in accordance with that specified in the product label.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 06 November 2024.

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