



VELETRI[®]
epoprostenol for Injection



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INDICATION

VELETRI[®] (epoprostenol) for Injection is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases (CTD).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VELETRI is contraindicated in patients with congestive heart failure due to severe left ventricular systolic dysfunction.

VELETRI should not be used chronically in patients who during dose initiation develop pulmonary edema, which may be associated with pulmonary veno-occlusive disease.

VELETRI is also contraindicated in patients with known hypersensitivity to the drug or to structurally related compounds.

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[Prescribing VELETRI](#)

[VELETRI for IPAH/HPAH](#)

[VELETRI for PAH/CTD](#)

[Dosing VELETRI](#)

[Administering VELETRI](#)

[Reconstituting VELETRI](#)

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Prescribing VELETRI

VELETRI for IPAH/HPAH

Exercise data in idiopathic or heritable pulmonary arterial hypertension (IPAH/HPAH) at 12 weeks

Increased Exercise Capacity¹

- In 2 prospective, open-label, randomized trials of 8 and 12 weeks' duration (pooled data results) in patients with idiopathic pulmonary arterial hypertension (IPAH) or heritable PAH (HPAH) NYHA Functional Class III or IV, except for 2 patients with NYHA Functional Class II, statistically significant improvement was observed in exercise capacity, as measured by the 6-Minute Walk Test in patients who received continuous intravenous epoprostenol plus conventional therapy compared to those who received conventional therapy alone. Improvements were apparent as early as the first week of therapy.
- Conventional therapy could include anticoagulants, oral vasodilators, supplemental oxygen, digoxin, and/or diuretics.

REFERENCE: 1. VELETRI® (epoprostenol) for Injection full prescribing information. Actelion Pharmaceuticals US, Inc. June 2012.

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WARNINGS AND PRECAUTIONS

General

Reconstitute VELETRI only as directed using Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. Do not mix VELETRI with any other parenteral medications or solutions prior to or during administration. Each vial is for single use only; discard any unused solution. Use after reconstitution and immediate dilution to final concentration. Use at room temperature (77°F/25°C). Do not expose VELETRI to direct sunlight.

VELETRI should be used only by clinicians experienced in the diagnosis and treatment of pulmonary hypertension.

Dose Initiation

VELETRI is a potent pulmonary and systemic vasodilator. Initiate VELETRI in a setting with adequate personnel and equipment for physiologic monitoring and emergency care. During dose initiation, asymptomatic increases in pulmonary artery pressure coincident with increases in cardiac output occurred rarely. In such cases, consider dose reduction, but such an increase does not imply that chronic treatment is contraindicated.

Chronic Use and Dose Adjustment

During chronic use, deliver VELETRI continuously on an ambulatory basis through a permanent indwelling central venous catheter. Unless contraindicated, administer anticoagulant therapy to patients receiving VELETRI to reduce the risk of pulmonary thromboembolism or systemic embolism through a patent foramen ovale. To reduce the risk of infection, use aseptic technique in the reconstitution and administration of VELETRI and in routine catheter care. Because epoprostenol is metabolized rapidly, even brief interruptions in the delivery of VELETRI may result in symptoms associated with rebound pulmonary hypertension including dyspnea, dizziness, and asthenia. Intravenous therapy with VELETRI will likely be needed for prolonged periods, possibly years, so consider the patient's capacity to accept and care for a permanent intravenous catheter and infusion pump.

Dosage of VELETRI during chronic use should be adjusted at the first sign of recurrence or worsening of symptoms attributable to pulmonary hypertension or the occurrence of adverse events associated with epoprostenol. Following dosage adjustments, monitor standing and supine blood pressure and heart rate closely for several hours.

Withdrawal Effects

Abrupt withdrawal (including interruptions in drug delivery) or sudden large reductions in dosage of VELETRI may result in symptoms associated with rebound pulmonary hypertension, including dyspnea, dizziness, and asthenia. Abrupt withdrawal should be avoided.

ADVERSE EVENTS

The most common and dose-limiting adverse events during dose initiation and escalation (≥1%) were flushing (58%), headache (49%), nausea/vomiting (32%), hypotension (16%), anxiety/nervousness/agitation (11%), chest pain (11%), dizziness (8%), bradycardia (5%), abdominal pain (5%), musculoskeletal pain (3%), dyspnea (2%), back pain (2%), sweating (1%), dyspepsia (1%), hypesthesia/paresthesia (1%), and tachycardia (1%).

Adverse events occurring in patients with idiopathic or heritable PAH with ≥10% difference between epoprostenol and conventional therapy alone were chills/fever/sepsis/flu-like symptoms (25% vs 11%), tachycardia (35% vs 24%), flushing (42% vs 2%), diarrhea (37% vs 6%), nausea/vomiting (67% vs 48%), jaw pain (54% vs 0%), myalgia (44% vs 31%), nonspecific musculoskeletal pain (35% vs 15%), anxiety/nervousness/tremor (21% vs 9%), dizziness (83% vs 70%), headache (83% vs 33%), and hypesthesia/hyperesthesia/paresthesia (12% vs 2%).

Adverse events occurring in patients with PAH/CTD with ≥10% difference between epoprostenol and conventional therapy alone were flushing (23% vs 0%), hypotension (13% vs 0%), anorexia (66% vs 47%), nausea/vomiting (41% vs 16%), diarrhea (50% vs 5%), jaw pain (75% vs 0%), pain/neck pain/arthritis (84% vs 65%), headache (46% vs 5%), skin ulcer (39% vs 24%), and eczema/rash/urticarial (25% vs 4%).

Thrombocytopenia has been reported during uncontrolled clinical trials in patients receiving epoprostenol.

Potential adverse events from postmarketing evaluations include anemia, hypersplenism, pancytopenia, splenomegaly, and hyperthyroidism.

Although the relationship to epoprostenol administration has not been established, pulmonary embolism has been reported in several patients taking epoprostenol and there have been reports of hepatic failure.

DRUG INTERACTIONS

Additional reductions in blood pressure may occur when VELETRI is administered with diuretics, antihypertensive agents, or other vasodilators. When other antiplatelet agents or anticoagulants are used concomitantly, there is the potential for VELETRI to increase the risk of bleeding. However, patients receiving infusions of epoprostenol in clinical trials were maintained on anticoagulants without evidence of increased bleeding. In clinical trials, epoprostenol was used with digoxin, diuretics, anticoagulants, oral vasodilators, and supplemental oxygen.

VELETRI for PAH/CTD

Dosing VELETRI

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VELETRI[®] (epoprostenol) for Injection Patient Enrollment Form

To start patients on VELETRI, healthcare professionals must complete the standard Enrollment Form.

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For Veterans Affairs hospitals only, use the VA Enrollment Form.

[VA Enrollment Form](#)

Enter your email address and click Submit to receive a link to the selected enrollment form.

VELETRI Patient Enrollment Form

VA Enrollment Form

Email:

Submit

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