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FIRST TIME GENERIC APPROVAL

Brand Name	Flolan®
Generic Name	epoprostenol
Drug Manufacturer	Sun Pharmaceutical Industries, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic Approval

FDA APPROVAL DATE

January 15, 2021

LAUNCH DATE

FDB addition date: January 22, 2021

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

New Drug Application (ANDA): 210473

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Epoprostenol sodium is a prostanoid vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

MECHANISMS OF ACTION

Epoprostenol has 2 major pharmacological actions: (1) direct vasodilation of pulmonary and systemic arterial vascular beds, and (2) inhibition of platelet aggregation.

DOSE FORM AND STRENGTH

For injection: 0.5 mg or 1.5 mg of epoprostenol powder in a single-dose vial

DOSE & ADMINISTRATION

Dosage

- Initiate intravenous infusion through a central venous catheter at 2 ng/kg/min.
- Change dose in 1 to 2 ng/kg/min increments at intervals of at least 15 minutes based on clinical response.
- Avoid sudden large dose reductions.

Administration

Epoprostenol for injection is administered by continuous intravenous infusion via a central venous catheter using an ambulatory infusion pump. Do not mix with any other parenteral medications or solutions prior to or during administration.