Epoprostenol

(Flolan, Veletri)

Updated September 2023

Epoprostenol is an intravenous medication approved for the treatment of pulmonary arterial hypertension, also known as Group 1 pulmonary hypertension. The goal of this therapy is to improve the ability to exercise and improve symptoms such as shortness of breath and tiredness.

In 1995, Flolan was the first drug approved by the Food and Drug Administration to treat pulmonary arterial hypertension. Epoprostenol also is available as a generic and by the brand name Veletri.

How epoprostenol works

Epoprostenol is a manufactured prostacyclin. Prostacyclins are naturally occurring substances in the body that affect dilating blood vessels. In pulmonary arterial hypertension, the lung blood vessels narrow, making it difficult to push blood from the right side of the heart into the lungs. The drug dilates the narrowed blood vessels in the lungs. Relaxing and widening blood vessels in the lungs decreases lung pressures, reduces strain on the right heart and improves heart function. Lower lung pressure and improved heart function generally improves the ability to be more active.

Dosing and administration

Epoprostenol for injection is administered continuously via a portable pump. It is delivered through a thin tube called a catheter into a large vein near the heart. One end of the catheter is surgically implanted in the chest and the other end is attached to a small, portable pump (CADD Legacy Pump). The pump stores the medication and keeps it flowing into the body. Your pump should always be on, and you must carry or wear the pump at all times.

When you begin treatment, you typically will be hospitalized for several days. Your health care team, including your PH doctor and nurse coordinator, pharmacists and specialty nurses, will guide you step-by-step to prepare, use and store your medication. Your health care team also will show you how to care for your central line, prevent infection, operate the pump and troubleshoot problems with the pump.

To avoid potential interruptions in drug delivery, be sure to have access to a backup infusion pump and intravenous infusion sets, including a backup cassette.

Your health care provider will determine the dose you need. Generally, you will start epoprostenol at a low dose (1-2 ng/kg/min) in the hospital. Your dose will be increased incrementally a few times a day depending on how well you tolerate the medicine.

After you’re discharged, you can increase your dose every few days. Your dose may change during the course of
Preparing and storing your medication

**Veletri**: You must mix vials of Veletri powder and dilute it with commercially available sterile water for injection USP, or sodium chloride 0.9% injection USP. Veletri shouldn’t be mixed with other solutions or medications before or during administration. Each vial is for single use only; discard unused solution.

After mixing the powder with the sterile water or sterile saline, you must transfer 100 mL to an infusion cassette that fits in the small battery-powered pump. This process must be done carefully to avoid accidentally adding bacteria (which could cause infection) to the medicine.

When you start Veletri IV therapy, you can prepare and use your medicine immediately, or you can prepare up to eight cassettes in advance and store them in the refrigerator (36°F to 46°F/2°C to 8°C) for up to eight days. When prepared, stored and used as directed, you don’t need ice packs.

**Flolan**: Flolan comes in single-dose freeze-dried powder. Discard unused diluent or unused reconstituted solution.

Reconstitute Flolan only with pH 12 sterile diluent for Flolan. Add enough sterile diluent to make 100 mL for the infusion cassette that fits in CADD pump.

Don’t mix Flolan with other solutions or medications before or during administration.

Store freshly prepared Flolan or reconstituted in the refrigerator at 36°F to 46°F for no longer than eight days. Protect Flolan from light and don’t freeze reconstituted solutions.

Obtaining epoprostenol

Epoprostenol is a limited-distribution medication, which means it can’t be purchased at a local pharmacy. It must be prescribed by a physician, and insurance approval must be obtained before starting therapy. The drug is supplied by specialty pharmacies (Accredo Health Group and CVS Caremark), which also have teams of clinical pharmacists and nurses. Your specialty pharmacy team will help with all aspects of long-term epoprostenol use, including insurance issues and education about pump function and central line care. It also will provide pumps, supplies and 24-hour technical troubleshooting.

Insurance

Most health insurance plans will pay part of the cost of this medication. However, some plans still leave patients with high out-of-pocket responsibilities. Depending on your insurance plan, you may be eligible for assistance from the company that manufactures your drug or from a non-profit charitable assistance organization. Questions? Call PHA at 301-565-3004.
Common side effects

- Headache
- Diarrhea
- Nausea
- Jaw pain
- Flushing of the skin
- Dizziness
- Swelling
- Itching
- Muscle or joint pain
- Low systemic blood

In addition to side effects from the medicine, you might have side effects from the infusion system. Infection and bleeding can occur at the infusion site.

The half-life of epoprostenol is about three minutes. Stopping epoprostenol can be fatal when done abruptly.

Special considerations

**Pregnancy or breastfeeding:** Limited published data is available about epoprostenol when used during pregnancy. The data available hasn’t shown a link to major birth defects, miscarriages or adverse maternal or fetal outcomes when used during pregnancy.

Infused epoprostenol currently carries an FDA grading of “B” in pregnancy, which means it should be used during pregnancy when the benefit outweighs any risks.

There is no data on the presence of epoprostenol in human milk or the effects on breastfed infants. The developmental and health benefits of breastfeeding on the child and the mother’s clinical need for Flolan should be considered with potential adverse effects from epoprostenol on the child or underlying maternal conditions.

**Pediatric:** Safety and efficacy in pediatric patients has not been established. Epoprostenol has been used in children.

**Other:** Epoprostenol clearance appears to be reduced in patients with liver insufficiency. This may decrease tolerability. Patients with mild or moderate liver insufficiency might be started at lower initial doses and could be more sensitive to increases. Epoprostenol hasn’t been studied in people with severe liver disease.

Epoprostenol hasn’t been evaluated in patients with impaired kidney function. Since epoprostenol is mainly excreted through the kidney, reduced drug clearance could cause increased epoprostenol exposure and decreased tolerability. Likewise, the effect of dialysis is unknown.
**Allergies:** Possible but unlikely.

**Drug interactions**

No medications are prohibited with epoprostenol. (See package insert for full details.)