

Treprostinil — Injection



Product name

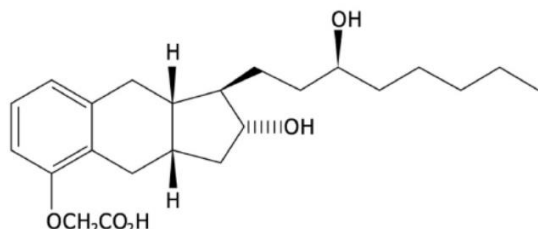
Generic name: Treprostinil Injection

Ingredient

The main ingredient of this product is treprostinil.

Chemical name: $[(1R,2R,3aS,9aS)-2,3,3a,4,9,9a\text{-hexahydro-2-hydroxy-1-}[(3S)\text{-3-hydroxyoctyl}]1H\text{-benz}[f]\text{inden-5-yl}]o\text{xy}]acetic\ acid$.

Chemical structure:



Molecular formula: $C_{23}H_{34}O_5$

Molecular weight: 390.52

Excipients: Sodium citrate, hydrochloric acid, m-cresol, sodium hydroxide, sodium chloride and water for injection.

Description

This product is a clear, colourless to slightly yellow solution.

Indication

This product is indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%).

Strength

20ml: 50mg

Dosage and administration

The drug can be administered with or without further dilution with sterile water for injection, or 0.9% sodium chloride injection prior to administration. This product could be administered by subcutaneous infusion and intravenous infusion. See Table 1 below for storage and administration time limits for the different diluents.

Table 1: Selection of diluent

Diluent	Storage Limits	Administration Limits
None	Same expiry date as the product	16 weeks at 40°C
Sterile Water for Injection 0.9% Sodium Chloride for Injection	4 hours at room temperature or 24 hours refrigerated	48 hours at 40°C