 Each mL contains: 1 mg Treprostinil

Usual Dosage: See package insert.
Storage: See package insert. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Prior to intravenous infusion, Treprostinil Injection must be diluted with Sterile 0.9% Sodium Chloride Solution or Water for Injection.
06-2014M
Manufactured in Canada by Sandoz Canada Inc. for Sandoz Inc., Princeton, NJ 08540
NDC 0781-3425-80
Treprostinil Injection
50 mg/20 mL
(2.5 mg/mL)
For Subcutaneous or Intravenous Infusion Only
Sterile
20 mL Multi-dose Vial
Rx only

Each mL contains: 2.5 mg Treprostinil
Usual Dosage: See package insert.
Storage: See package insert. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Prior to intravenous infusion, Treprostinil Injection must be diluted with Sterile 0.9% Sodium Chloride Solution or Water for Injection.

06-2014M
Manufactured in Canada by Sandoz Canada Inc. for Sandoz Inc., Princeton, NJ 08540
Treprostinil Injection
100 mg/20 mL
(5 mg/mL)
For Subcutaneous or Intravenous Infusion Only
Sterile
20 mL Multi-dose Vial
Rx only
SANDOZ

Each mL contains: 5 mg Treprostinil
Usual Dosage: See package insert.
Storage: See package insert. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Prior to intravenous infusion, Treprostinil Injection must be diluted with Sterile 0.9% Sodium Chloride Solution or Water for Injection.
06-2014M
Manufactured in Canada by Sandoz Canada Inc. for Sandoz Inc., Princeton, NJ 08540

Lot Exp
Each mL contains: 10 mg Treprostinil
Usual Dosage: See package insert.
Storage: See package insert. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Prior to intravenous infusion, Treprostinil Injection must be diluted with Sterile 0.9% Sodium Chloride Solution or Water for Injection.
06-2014M
Manufactured in Canada by Sandoz Canada Inc. for Sandoz Inc., Princeton, NJ 08540
Each mL contains: 1 mg Treprostinil. Each mL also contains 6.3 mg sodium citrate, 5.3 mg sodium chloride, 3 mg metacresol. Hydrochloric acid and sodium hydroxide may have been added to adjust pH.

Prior to intravenous infusion, Treprostinil Injection must be diluted with Sterile 0.9% Sodium Chloride Solution or Water for Injection.
Each mL contains:
2.5 mg Treprostinil
Each mL also contains 6.3 mg sodium citrate, 5.3 mg sodium chloride, 3 mg metacresol.
Hydrochloric acid and sodium hydroxide may have been added to adjust pH.

Prior to intravenous infusion, Treprostinil Injection must be diluted with Sterile 0.9% Sodium Chloride Solution or Water for Injection.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Manufactured in Canada by Sandoz Canada Inc. for Sandoz Inc., Princeton, NJ 08540

06-2014

Treprostinil Injection

100 mg/20 mL
(5 mg/mL)

For Subcutaneous or Intravenous Infusion Only

Sterile

20 mL Multi-dose Vial Rx only

NDC 0781-3427-80

Each mL contains:
5 mg Treprostinil each mL also contains 6.3 mg sodium citrate, 5.3 mg sodium chloride, 3 mg metacresol. Hydrochloric acid and sodium hydroxide may have been added to adjust pH.

Prior to intravenous infusion, Treprostinil Injection must be diluted with sterile 0.9% Sodium Chloride Solution or Water for Injection.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
Each mL contains:
10 mg Treprostinil
Each mL also contains
6.3 mg sodium citrate,
4 mg sodium chloride,
3 mg metacresol.
Hydrochloric acid and
sodium hydroxide may
have been added to
adjust pH.

Prior to intravenous
infusion, Treprostinil
Injection must be
diluted with Sterile
0.9% Sodium Chloride
Solution or Water for
Injection.

Store at 20°-25°C
(68°-77°F) [see USP
Controlled Room
Temperature].

KEEP THIS AND ALL
DRUGS OUT OF THE
REACH OF
CHILDREN.
1 INDICATIONS AND USAGE

1.1 Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to diminish the symptoms of PAH and improve functional capacity in adults with idiopathic or heretofore attributed causes (e.g., congenital systemic-to-pulmonary shunts, or PAH associated with congenital heart defects patients who have undergone surgical repair of congenital heart defects). See [see Clinical Studies (14.1)].

1.2 Prostacyclin Vasodilator (vasodilator therapy) to diminish the symptoms of PAH and improve functional capacity in adults with PAH associated with congenital systemic-to-pulmonary shunts (23%) or PAH associated with congenital heart defects. See [see Clinical Studies (14.1)].

3 ADMINISTRATION AND DOSAGE

3.1 Patients With Congenital Heart Defects

3.1.1 Congenital Systemic-to-Pulmonary Shunts

3.1.2 Congenital Heart Defects

3.1.3 Pulmonary Arterial Hypertension

3.2 Precautions

3.2.1 Cardiovascular Treatment

3.2.2 Pulmonary Arterial Hypertension

3.2.3 Concomitant Administration

3.2.4 Monitoring

3.2.5 Monitoring of Hemodynamic Response

3.2.6 Monitoring of Procedural Intolerance

4 SIDE EFFECTS

4.1 General

4.2 Hemodynamic

4.3 Hemorrhage

4.4 Respiratory

4.5 Infection

4.6 Neurologic

4.7 Gastrointestinal

4.8 Skin

4.9 Laboratory

4.10 Other Side Effects

5 ADVERSE REACTIONS

5.1 Administration

5.2 Worsening PAH upon Abrupt Withdrawal or Decrease in Dosage

5.3 Effects of Unintentional IV Stopped

5.4 Effect of Other Drugs on Treprostinil

6 DRUG INTERACTIONS

6.1 Prostacyclin and Prostacyclin Analog

6.2 CYP2C8 Enzymes

6.3 Drugs Influencing CYP2C8 Enzymes

7 USE IN SPECIFIC POPULATIONS

7.1 Pregnancy

7.2 Lactation

7.3 Children

7.4 Geriatric Use

7.5 Renal Impairment

7.6 Hepatic Impairment

8 HUMAN PHARMACOLOGY

8.1 Clinical Pharmacology

8.2 Pharmacokinetics

8.3 Pharmacodynamics

9 DOSAGE FORMS AND STRENGTHS

10 CONCOMITANT DRUGS

11 PATIENT COUNSELING INFORMATION
Diarrhea, jaw pain, edema, vasodilatation, and nausea, and these are generally considered ""