A step-by-step programming guide

For needle and needle-free **systems**

This guide provides detailed instructions on the reconstitution, dilution, and storage of VELETRI®. It is intended to be used after your healthcare professional has provided you with step-by-step instructions about preparing and using VELETRI®.

What is VELETRI® (epoprostenol) for Injection?

VELETRI® is a prescription medicine that is given intravenously (in a vein). It is used to treat adults with certain kinds of severe pulmonary arterial hypertension (PAH) (WHO Group 1), a condition in which blood pressure is too high in the blood vessels between the heart and the lungs. VELETRI® may improve your ability to exercise as measured by how far you can walk in 6 minutes (6-minute walk test).

Studies showing VELETRI® is effective included mainly patients with NYHA Functional Class III-IV PAH. In these patients, PAH was caused by unidentified or hereditary factors or connective tissue disease.

Who should not take VELETRI®?

VELETRI® should not be used if you have heart failure due to severe left heart disease, if you develop fluid in the lungs (pulmonary edema) when starting therapy, or if you are allergic to epoprostenol.

Some medications may interact with VELETRI®. Please talk to your doctor about all of your medications.

VELETRI® epoprostenol for Injection

Please see full Prescribing Information.

INDICATION AND IMPORTANT SAFETY INFORMATION

What is VELETRI® (epoprostenol) for Injection?
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VELETRI® should not be used if you have heart failure due to severe left heart disease, if you develop fluid in the lungs (pulmonary edema) when starting therapy, or if you are allergic to epoprostenol.

Some medications may interact with VELETRI®. Please talk to your doctor about all of your medications.

What is the most important information I should know about VELETRI®?
It is important to use VELETRI® as directed by your doctor. VELETRI® should be used only with Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. Do not mix VELETRI® with other intravenous medications. Each vial is for single use only; discard any unused medication. Use at room temperature (77°F/25°C). Do not expose VELETRI® to direct sunlight.

When you take epoprostenol for the first time, you must be in a setting (hospital or clinic) where you can be monitored for any serious side effects or in case of emergency. Your blood pressure and heart rate should also be monitored with any dose changes. If you are taking VELETRI®, your doctor may prescribe another kind of medicine used to prevent blood clots. It is the use of these medications concomitantly (in combination) with VELETRI® that may potentially cause an increase in the risk of bleeding.

Sudden and dramatic changes in dose may lead to unstable blood pressure, a return of pulmonary hypertension symptoms, or fatal low blood pressure (hypotension). Do not stop using VELETRI® without first talking to your doctor.

To reduce the risk of infection in the bloodstream, it is important to know how to properly care for the catheter and infusion pump.

What are the possible side effects of VELETRI®?

You may have side effects at the start of treatment or with dose increases. The most common side effects seen in at least 1% of patients were: flushing, headache, nausea/vomiting, low blood pressure, anxiety/nervousness, chest pain, dizziness, slow heartbeat, abdominal pain, pain in the muscles and/or ligaments and bones, shortness of breath, back pain, sweating, upset stomach, numbness/increased sensitivity, and fast heartbeat.

The most common side effects in patients with PAH due to unidentified or hereditary factors with at least 10% difference between the group that received epoprostenol and the group that received conventional therapy alone were: flu-like symptoms, fast heartbeat, flushing, diarrhea, nausea/vomiting, jaw pain, pain in the muscles and/or ligaments and bones, anxiety/nervousness, dizziness, headache, and numbness/increased sensitivity/tingling.

The most common side effects in patients with PAH due to connective tissue disease with at least 10% difference between the group that received epoprostenol and the group that received conventional therapy alone were: flushing, low blood pressure, lack of appetite, nausea/vomiting, diarrhea, jaw pain, neck/joint pain, headache, skin ulcer, and rash.

Talk to your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of VELETRI®. For more information, ask your doctor or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information for VELETRI® and discuss any questions you have with your doctor.

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VELETRI®
epoprostenol for Injection

Storage of prepared medication

The instructions in this guide must be followed to ensure that the drug retains its stability and that the proper dose is delivered.

- Mixed (reconstituted) or diluted medication should be protected from direct sunlight
- Dilute immediately after reconstitution. Do not store reconstituted medication in the vial
- Fully diluted cassettes may be stored for up to 8 days in the refrigerator (36°F to 46°F/2°C to 8°C). Your healthcare professional or specialty pharmacy nurse will direct you on how to store your prepared medication

Your healthcare professional will determine the best concentration, storage, and administration schedule for you.

For more information about storing VELETRI® (epoprostenol) for Injection, please refer to the full Prescribing Information and talk to your healthcare professional.

For mechanical concerns pertaining to your Infusion pump or its components, including questions about the device's proper functioning and any alarms, please contact your specialty pharmacy immediately.

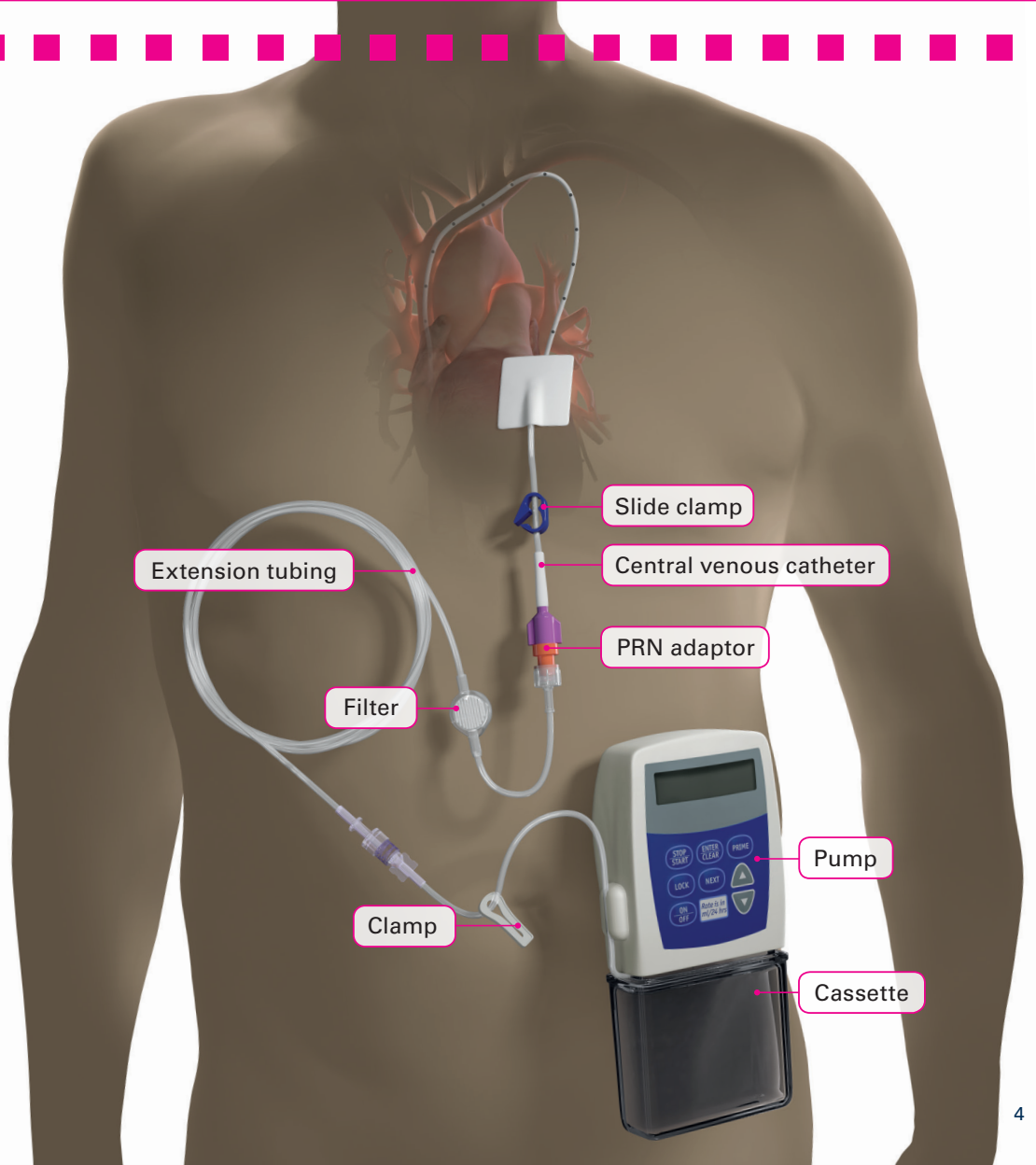
For ordering and shipment questions, please contact your specialty pharmacy as well.

VELETRI®
epoprostenol for Injection

Your VELETRI® continuous administration system

The VELETRI® (epoprostenol) for Injection administration system is designed to maintain continuous, steady VELETRI® dosing, 24 hours a day, at the concentration prescribed by your physician.

Images may vary from actual pump.
Please follow pump manufacturer guidelines.



Preparing the work area

This is a very important step because bacterial contamination can lead to serious infections in individuals on intravenous drug therapy.

To help prevent infection, clean the area where you will be preparing VELETRI® (epoprostenol) for Injection with disinfectant wipes or 70% alcohol. Let the surface air-dry. Follow these directions again if the area becomes contaminated during use.

Also, thoroughly wash your hands with soap and warm water for a minimum of 20 seconds, and then dry prior to reconstituting, diluting, and administering VELETRI®. If you must leave the work area before completing the process, be sure to **thoroughly wash and dry your hands again.**

Decrease the chance of infection by keeping your work area clean.

VELETRI® epoprostenol for Injection

Needle-free system

Identifying and gathering equipment

Make sure you have all the necessary supplies gathered in your work area prior to beginning. Generally, these supplies include:

- **A** Vial(s) of VELETRI® (epoprostenol) for Injection 0.5 mg **or** 1.5 mg powder

Two 50-mL vials of either

- **B1** Sterile Water for Injection, USP, **or**
- **B2** Sodium Chloride 0.9% Injection, USP (normal saline)
- **C** One 100-mL medication cassette
- **D** Two 50- or 60-mL syringes
- **E1** MINI-SPIKE® Dispensing Pins, **or**
- **E2** Q-Syte™ Needle-Free Vial Adapters
- **F** Alcohol pads
- **G** Extension tubing with 0.22 micron filter
- **H** Pump (batteries, if needed)
- **I** Cassette labels

Images may vary from actual pump.
Please follow pump manufacturer guidelines.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle-free system

1

Wash your hands and clean your work surface with disinfectant wipes or 70% alcohol.

See page 5 for detailed instructions.

2

Be sure to check the expiration dates on all medication and diluent vials prior to mixing.

Remove the caps from the vial(s) of VELETRI® (epoprostenol) for Injection and from the normal saline (NS) or sterile water (SW).

If you are using the 0.5 mg vial of VELETRI®, the cap will be white. The cap for the 1.5-mg vial will be red.

3

Clean the rubber stoppers of the vials of VELETRI® and NS or SW with a disinfectant or antiseptic pad, or a pad with 70% alcohol.

Important: VELETRI® is stable only when reconstituted as directed using Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. VELETRI® must not be reconstituted or mixed with any other intravenous medications or solutions prior to or during administration. The same solution must be used for both reconstituting and diluting VELETRI®. Do not combine sterile water with normal saline when preparing VELETRI®.

These solutions are commercially available and can be purchased from either regular or specialty pharmacies.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle-free system (continued)

4

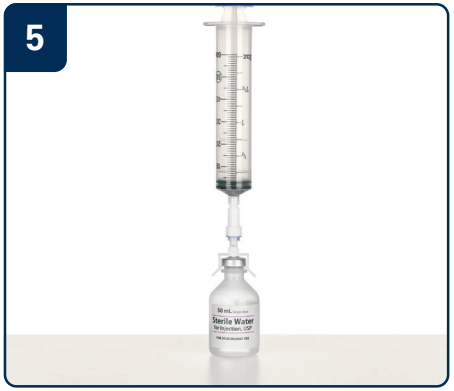
Remove 2 spikes/adapters from the sterile packaging. **Do not touch the spikes or the threaded connectors.**

Insert 1 spike/adapter into the rubber stopper on each vial of NS or SW. Insert 1 spike/adapter into the rubber stopper on the vial of powdered VELETRI® (epoprostenol) for injection medication. Place the vials on your clean work surface.

The vials of VELETRI® should have the MINI-SPIKE® Dispensing Pins, or Q-Syte™ Needle-Free Vial Adapters.

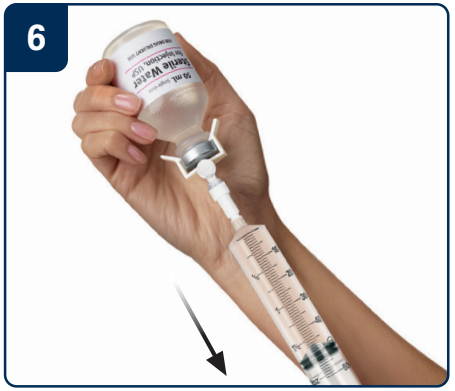
Clean the top of each spike/adapter with a disinfectant or antiseptic pad, or a pad with 70% alcohol. Use a separate pad for each spike/adapter being used in the mixing process.

5



Screw the 60-mL syringe onto the threaded connector on the top of the spike/adapter.

6



With the syringe attached to the vial, turn the vial upside down.

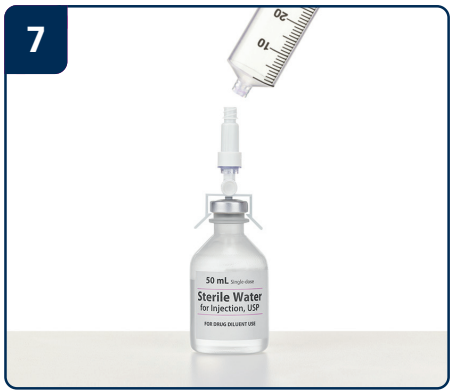
Pull the plunger back to withdraw 50 mL. Be sure to remove all air bubbles.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle-free system (continued)

7

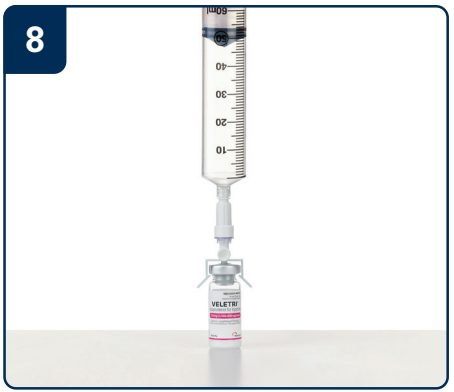


Unscrew the syringe from the spike/adapter.

With tip of syringe straight up, tap syringe to move all bubbles to the top, and push out all excess air.

Remove excess fluid and measure to the 50-mL line.

8



Screw the syringe filled with NS or SW to the threaded connector on top of the spike/adapter attached to the vial of VELETRI® (epoprostenol) for Injection.

9

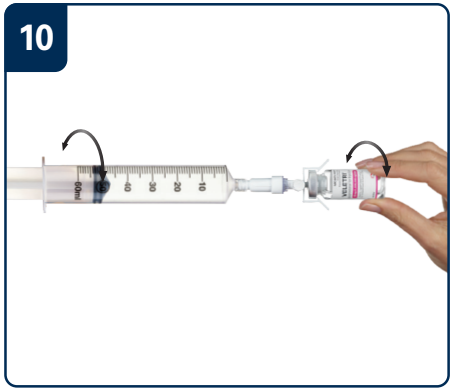
Slowly inject 5 mL of NS or SW, making sure to prevent turbulence and foaming of the medication.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle-free system (continued)

10

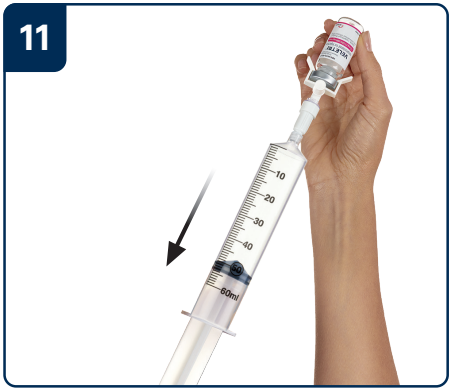


Do not shake. Gently roll the vial of VELETRI® (epoprostenol) for Injection in your hands until the powder is completely dissolved and the solution is clear.

Keeping the syringe and the spike/adapter together, turn the vial upside down to dissolve any undissolved powder that may be present near the top of the vial. Cloudiness and particles should not be present in the solution.

If cloudiness or particles are present, do not continue using this vial. Prepare a new vial of VELETRI®. Notify your Specialty Pharmacy of the unusable vial.

11



Draw back all of the medication from the vial into the 60-mL syringe.*

Unscrew the syringe and place it on your clean work surface or back in its plastic holder.

Repeat reconstitution Steps 8 through 11 if more than 1 vial of VELETRI® is being used.

You are now ready to fill the medication cassette.

*For patients diluting to a final concentration of 3000 ng/mL, please discuss this step with your healthcare professional. The amount you draw back will be different.

Important: VELETRI® is stable only when reconstituted as directed using Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. VELETRI® must not be reconstituted or mixed with any other intravenous medications or solutions prior to or during administration. The same solution must be used for both reconstituting and diluting VELETRI®. Do not combine sterile water with normal saline when preparing VELETRI®.

These solutions are commercially available and can be purchased from either regular or specialty pharmacies.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Diluting the medication and filling the medication cassette: needle-free system

Next, remove the cap from the end of the medication cassette.

Be careful not to touch the end of the exposed tubing.

Screw the syringe onto the end of the tubing and inject all the liquid from the syringe into the cassette.

Note: Close the slide clamp on the reservoir tubing after filling it with solution; otherwise, the medication will flow out.

Leave the syringe attached to act as a cap.

Repeat reconstitution Steps 5-7 with a second vial of NS or SW, drawing up a total of 50 mL of fluid. The total volume in the medication cassette will then equal 100 mL.

Next, attach the second 60-mL syringe and cassette tubing together. Unclamp the tubing and inject all fluid into the cassette. Close the slide clamp of the cassette tubing, leaving the syringe attached to the tubing.

Note: The same solution must be used for both reconstituting and diluting VELETRI® (epoprostenol) for Injection. Do not combine sterile water with normal saline when preparing VELETRI®.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Diluting the medication and filling the medication cassette: needle-free system (continued)

4

Rotate cassette back and forth 10 times. To remove excess air, tilt the cassette so that all air bubbles rise to the corner of the cassette where the tubing is attached.

Helpful hint: Place the cassette in a clean mug with the tubing and syringe hanging down on one side and the air in the upper corner near the blue tab. This will allow you to use two hands for Step 5.

5

Unclamp the tubing to remove air from the cassette. Pull back the plunger until ALL the air is removed from the cassette and tubing.

6

Clamp the tubing and remove the syringe from the cassette tubing; then attach the new sterile cap that was provided in the package. The cassette's sterile cap may be either red or blue.

Each vial is for single use only. Check all VELETRI® (epoprostenol) vials to assure that all medication has been removed.

Fill out the cassette label and apply it to the cassette. The cassette is now ready.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Diluting the medication and filling the medication cassette: needle-free system (continued)

7

When you are ready to connect the cassette to the pump, remove the clip from the top of the cassette.

8

Connect the cassette by fitting the hooks onto the pivot pins at the base of the pump. Push the cassette up against the pump. Place the joined pump and cassette in an upright position on a steady surface. Secure the cassette by using a coin to turn the lock knob 90° counterclockwise until you feel it stop.

Patients can now move to the section "A step-by-step programming guide"

Images may vary from actual pump.
Please follow pump manufacturer guidelines.

For more information about storing VELETRI® (epoprostenol) for Injection, please refer to the full Prescribing Information and talk to your healthcare professional.

VELETRI® epoprostenol for Injection

Preparing the work area

This is a very important step because bacterial contamination can lead to serious infections in individuals on intravenous drug therapy.

To help prevent infection, clean the area where you will be preparing VELETRI® (epoprostenol) for Injection with disinfectant wipes or 70% alcohol. Let the surface air-dry. Follow these directions again if the area becomes contaminated during use.

Also, thoroughly wash your hands with soap and warm water for a minimum of 20 seconds, and then dry prior to reconstituting, diluting, and administering VELETRI®. If you must leave the work area before completing the process, be sure to **thoroughly wash and dry your hands again.**

Decrease the chance of infection by keeping your work area clean.

VELETRI® epoprostenol for Injection

Needle system

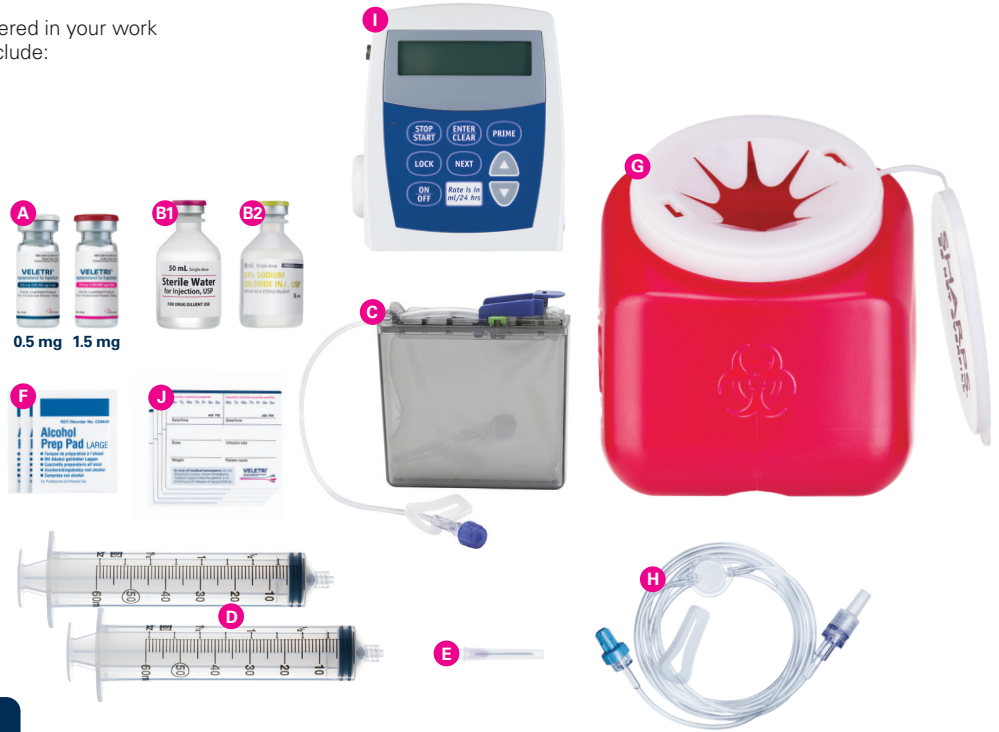
Identifying and gathering equipment

Make sure you have all the necessary supplies gathered in your work area prior to beginning. Generally, these supplies include:

- **A** Vial(s) of VELETRI® (epoprostenol) for Injection 0.5 mg **or** 1.5 mg powder

Two 50-mL vials of either

- **B1** Sterile Water for Injection, USP, **or**
- **B2** Sodium Chloride 0.9% Injection, USP (normal saline)
- **C** Infusion pump
- **D** Two 60-mL syringes
- **E** 18-gauge needle(s)
- **F** Alcohol pads
- **G** Sharps container
- **H** Extension tubing with 0.22 micron filter
- **I** Pump (batteries, if needed)
- **J** Cassette labels



Please ask your specialty pharmacy about the availability of a needle-free system.

Images may vary from actual pump.
Please follow pump manufacturer guidelines.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle system

1

Wash your hands and clean your work surface with disinfectant wipes or 70% alcohol.

See page 5 for detailed instructions.

2

Be sure to check the expiration dates on all medication and diluent vials prior to mixing.

Remove the caps from the vial of VELETRI® (epoprostenol) for Injection and from the normal saline (NS) or sterile water (SW).

If you are using the 0.5-mg vial of VELETRI®, the cap will be white. The cap for the 1.5-mg vial will be red.

3

Clean the rubber stoppers of the vials of VELETRI® and NS or SW with a disinfectant or antiseptic pad, or a pad with 70% alcohol.

Important: VELETRI® is stable only when reconstituted as directed using Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. VELETRI® must not be reconstituted or mixed with any other intravenous medications or solutions prior to or during administration. The same solution must be used for both reconstituting and diluting VELETRI®. Do not combine sterile water with normal saline when preparing VELETRI®.

These solutions are commercially available and can be purchased from either regular or specialty pharmacies.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle system (continued)

4

Attach an 18-gauge needle to a 60-mL syringe and pull back the plunger to the 50-mL mark. Insert the needle into the stopper on the vial of NS or SW.

5

Inject air into the NS or SW bottle until you feel resistance.

Be careful to avoid touching the plunger shaft.

6

Place the needle tip below the fluid surface; the air you injected into the bottle will draw fluid into the syringe. You may need to inject air into the bottle 2 or 3 times to draw the desired amount* of NS or SW. Once you have the desired amount of fluid drawn, remove the needle and set the syringe aside.

Repeat reconstitution Steps 2-6 for a second 60-mL syringe with NS or SW.

If you are using more than one vial of VELETRI® (epoprostenol), repeat reconstitution steps 2-3 to prepare another vial of VELETRI® for mixing.

*Desired amount is 50 mL.

Note: The same solution must be used for both reconstituting and diluting VELETRI® (epoprostenol) for Injection. Do not combine sterile water with normal saline when preparing VELETRI®.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle system (continued)

7

To add the prescribed amount of NS or SW to the powdered VELETRI® (epoprostenol) for Injection medication vial, insert the needle's tip bevel up (see inset) at a 45° angle into the rubber stopper.

8

Slowly inject 5 mL of NS or SW, making sure to prevent turbulence and foaming of the medication.

9

Do not shake. Gently roll the vial of VELETRI® (epoprostenol) for Injection in your hands until the powder is completely dissolved and the solution is clear.

Turn the vial upside down to dissolve any undissolved powder that may be present near the top of the vial. Cloudiness and particles should not be present in the solution.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Mixing (reconstitution) using the needle system (continued)

Draw back all of the medication from the vial into the 60-mL syringe.*

Repeat reconstitution Steps 7 through 10 if more than 1 vial of VELETRI® (epoprostenol) for Injection is being used.

Recap the syringe and put it down on your clean work surface. You are now ready to fill the medication cassette.

Note: Please be cautious when re-capping the needle. As there are alternatives to re-capping the needle, please discuss this step with your healthcare professional.

*For patients diluting to a final concentration of 3000 ng/mL, please discuss this step with your healthcare professional. The amount you draw back will be different.

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VELETRI® epoprostenol for Injection

Step-by-step instructions:

Diluting the medication and filling the medication cassette: needle system

Next, remove the cap from the end of the medication cassette.

Be careful not to touch the end of the exposed tubing.

Remove needle from syringe and attach the syringe to the tubing.

Add all the liquid from the syringe into the cassette.

Note: Close the slide clamp on the reservoir tubing after filling it with solution; otherwise, the medication will flow out.

Remove the empty syringe by unscrewing it.

Next, remove the needle from the second 60-mL syringe. Attach the syringe to the tubing on the medication cassette. Unclamp the tubing and inject the drug into the medication cassette. Close the slide clamp of the cassette tubing, leaving the syringe attached to the tubing.

Step-by-step instructions:

Diluting the medication and filling the medication cassette: needle system (continued)

4

Rotate cassette back and forth 10 times.
To remove excess air, tilt the cassette so that all air bubbles rise to the corner of the cassette where the tubing is attached.

5

Unclamp the tubing to remove air from the cassette. Pull back the plunger until ALL the air is removed from the cassette and tubing.

6

Clamp the tubing and remove the syringe from the cassette tubing; then attach the new sterile cap that was provided in the package.

Fill out the cassette label and apply it to the cassette. The cassette is now ready.

The cassette's sterile cap may be either red or blue.

VELETRI® epoprostenol for Injection

Step-by-step instructions:

Diluting the medication and filling the medication cassette: needle system (continued)

7

Discard all used needles and any other sharp materials in a **sharps container.**

Each vial is for single use only. Check all VELETRI® (epoprostenol) for Injection vials to assure that all medication has been removed.

8

When you are ready to connect the cassette to the pump, remove the clip from the top of the cassette.

9

Remove the blue clip on top of the cassette.

Connect the cassette by fitting the hooks onto the pivot pins at the base of the pump. Push the cassette up against the pump. Place the joined pump and cassette in an upright position on a steady surface. Secure the cassette by using a coin to turn the lock knob 90° counterclockwise until you feel it stop.

Images may vary from actual pump.
Please follow pump manufacturer guidelines.

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VELETRI®
epoprostenol for Injection

INDICATION AND IMPORTANT SAFETY INFORMATION

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VELETRI® is a prescription medicine that is given intravenously (in a vein). It is used to treat adults with certain kinds of severe pulmonary arterial hypertension (PAH) (WHO Group 1), a condition in which blood pressure is too high in the blood vessels between the heart and the lungs. VELETRI® may improve your ability to exercise as measured by how far you can walk in 6 minutes (6-minute walk test).

Studies showing VELETRI® is effective included mainly patients with NYHA Functional Class III-IV PAH. In these patients, PAH was caused by unidentified or hereditary factors or connective tissue disease.

Who should not take VELETRI®?
VELETRI® should not be used if you have heart failure due to severe left heart disease, if you develop fluid in the lungs (pulmonary edema) when starting therapy, or if you are allergic to epoprostenol.

Some medications may interact with VELETRI®. Please talk to your doctor about all of your medications.

What is the most important information I should know about VELETRI®?
It is important to use VELETRI® as directed by your doctor. VELETRI® should be used only with Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. Do not mix VELETRI® with other intravenous medications. Each vial is for single use only; discard any unused medication. Use at room temperature (77°F/25°C). Do not expose VELETRI® to direct sunlight.

When you take epoprostenol for the first time, you must be in a setting (hospital or clinic) where you can be monitored for any serious side effects or in case of emergency. Your blood pressure and heart rate should also be monitored with any dose changes. If you are taking VELETRI®, your doctor may prescribe another kind of medicine used to prevent blood clots. It is the use of these medications concomitantly (in combination) with VELETRI® that may potentially cause an increase in the risk of bleeding.

Sudden and dramatic changes in dose may lead to unstable blood pressure, a return of pulmonary hypertension symptoms, or fatal low blood pressure (hypotension). Do not stop using VELETRI® without first talking to your doctor.

To reduce the risk of infection in the bloodstream, it is important to know how to properly care for the catheter and infusion pump.

What are the possible side effects of VELETRI®?

You may have side effects at the start of treatment or with dose increases. The most common side effects seen in at least 1% of patients were: flushing, headache, nausea/vomiting, low blood pressure, anxiety/nervousness, chest pain, dizziness, slow heartbeat, abdominal pain, pain in the muscles and/or ligaments and bones, shortness of breath, back pain, sweating, upset stomach, numbness/increased sensitivity, and fast heartbeat.

The most common side effects in patients with PAH due to unidentified or hereditary factors with at least 10% difference between the group that received epoprostenol and the group that received conventional therapy alone were: flu-like symptoms, fast heartbeat, flushing, diarrhea, nausea/vomiting, jaw pain, pain in the muscles and/or ligaments and bones, anxiety/nervousness, dizziness, headache, and numbness/increased sensitivity/tingling.

The most common side effects in patients with PAH due to connective tissue disease with at least 10% difference between the group that received epoprostenol and the group that received conventional therapy alone were: flushing, low blood pressure, lack of appetite, nausea/vomiting, diarrhea, jaw pain, neck/joint pain, headache, skin ulcer, and rash.

Talk to your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of VELETRI®. For more information, ask your doctor or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information for VELETRI® and discuss any questions you have with your doctor.

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VELETRI® epoprostenol for Injection