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SB 486 Safe Needle Disposal Plan for 2012 - 2013

Submitted to:

**Department of Resources Recycling and Recovery
(CalRecycle)**

June 22, 2012

Background

The State of California has enacted two laws to address home generated sharps disposal. The first law (SB 1305), makes it illegal for any person in the state of California to dispose of home generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container. This law became effective September 1, 2008. In 2009, California enacted (SB 486) which requires any pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste devices. This plan is due on July 1, 2010 and annually thereafter.

Dr. Reddy's Laboratories, Inc. Self-Injectable Products

Subject To These Regulations In California

Dr. Reddy's Laboratories, Inc. currently markets, distributes, and/or sells one self-injectable product in the State of California. The generic name of this product is fondaparinux sodium injection (subcutaneous).

Dr. Reddy's Laboratories, Inc. Supports Safe Collection

and Proper Disposal of Home Generated Sharps

Dr. Reddy's Laboratories, Inc. supports appropriate and safe disposal of home-generated waste sharps. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned product was being developed. During the development of fondaparinux sodium injection (subcutaneous), Dr. Reddy's Laboratories, Inc. employed safe needle technology in order to protect patients and those assisting in the disposal of waste sharps. Specifically, fondaparinux sodium injection uses a 27 gauge needle that is only a half-inch long and an automatic needle protection system covers the needle after the injection. The steps to activate the automatic needle protection system are described in the fondaparinux sodium injection (subcutaneous) Patient Information Leaflet.

Automatic Needle Protection System:

The different parts of fondaparinux sodium safety syringe are:	
<ol style="list-style-type: none">1. Rigid Needle Shield2. Plunger3. Finger-grip4. Safety shield	
Syringe BEFORE USE	Syringe AFTER USE
	

Patient Education Materials:

Patients who self-inject Dr. Reddy's Laboratories, Inc. products at home should receive instructions from their healthcare professionals on how to use fondaparinux sodium injection properly. The full prescribing information for fondaparinux sodium injection is available to healthcare professionals. Patients should read the Patient Information Leaflet that comes with fondaparinux sodium injection before they start taking it and each time the prescription is refilled as there may be new information.

Dr. Reddy's Laboratories, Inc. has also created a patient specific website for fondaparinux sodium injection at www.reddyfondaparinux.com. This website provides patients with the most important information they need to know about fondaparinux sodium injection from Dr. Reddy's Laboratories. The information on this website does not take the place of talking with the patient's doctor about the medical condition or treatment. Patients can view fondaparinux sodium injection self-administration instructions in English or Spanish in text (by downloading a printable pdf document) or as a video.

Patients and caregivers can also contact a Dr. Reddy's Laboratories, Inc. representative at 1-888-375-3784. Pharmacists are available Monday through Friday 9:00 am to 7:00 pm EST to assist with questions about fondaparinux sodium injection.

Disposal:

Patients and consumers have several options available to them to safely dispose sharps waste.

Patients may visit California's CalRecycle website at <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm> to become familiar with all disposal options available and select the option that is most convenient. Below is a summary of the disposal options detailed on the California CalRecycle website:

1. Patients may use the *The Sharps and Medication Disposal Directory* to identify the locations of sites where sharps containers can be properly disposed. Patients can access this searchable database via the California CalRecycle website at: <http://www.calrecycle.ca.gov/HomeHazWaste/HealthCare/Collection/>
2. Patients may contact their health care provider or pharmacist for information on where to bring waste sharps.
3. Patients may contact their local household hazardous waste agency and ask if they collect sharps at their collection facilities or on household hazardous waste days.

Company Contact Information:

If you would like assistance from Dr. Reddy's Laboratories, Inc. in identifying your disposal options, please contact a Dr. Reddy's Laboratories, Inc. representative at 1-888-375-3784. Representatives are available to assist patients with questions about fondaparinux sodium injection, including product administration and medical waste disposal.

Dr. Reddy's Laboratories, Inc. remains committed to help facilitate the safe disposal of its products and will continue to evaluate feedback and make modifications to this plan as needed.

PATIENT INFORMATION

Fondaparinux Sodium Injection

Read the Patient Information that comes with fondaparinux sodium injection before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about fondaparinux sodium injection, ask your doctor or pharmacist.

What is the most important information I should know about fondaparinux sodium injection?

Certain medical procedures involving the spine, such as an epidural (pain medication given through the spine), spinal anesthesia, or spinal puncture, may be used during your hospital stay. If you need any of these procedures while receiving fondaparinux sodium injection, heparins, heparinoids, or low-molecular weight heparins (anticoagulants), you may be at risk for having a blood clot (hematoma) in or around your spine. This type of clot is very serious, as it can cause long-term and possibly permanent paralysis (loss of the ability to move).

If you receive fondaparinux sodium injection after an epidural or spinal anesthetic is used, as the anesthesia for your surgery, your doctor will watch you closely for problems with feeling (sensation) and being able to move. Tell your doctor right away if you have any of these signs and symptoms, especially in your legs and feet:

- tingling
- numbness
- muscle weakness

Because the risk of bleeding may be higher, tell your doctor before taking fondaparinux sodium if you:

- are also taking certain other medicines that affect blood clotting such as aspirin, an NSAID (for example, ibuprofen or naproxen), clopidogrel, or warfarin sodium.
- have bleeding problems.
- had problems in the past with pain medication given through the spine.
- have had surgery to your spine.
- have a spinal deformity.

What is fondaparinux sodium injection?

Fondaparinux sodium injection is a prescription medicine that “thins your blood” (also known as an anticoagulant). Fondaparinux sodium injection is used to:

- help prevent blood clots from forming in patients who have had certain surgeries of the hip, knee, or the stomach area (abdominal surgery)
- treat people who have blood clots in their legs or blood clots that travel to their lungs

It is not known if fondaparinux sodium injection is safe and effective for use in children younger than 18 years of age.

Who should not take fondaparinux sodium injection?

Do not take fondaparinux sodium injection if you have:

- certain kidney problems
- active bleeding problems
- an infection in your heart
- low platelet counts and if you test positive for a certain antibody while you are taking fondaparinux sodium injection.

People who weigh less than 110 pounds (50 kg) should not use fondaparinux sodium injection to prevent blood clots from forming after surgery.

What should I tell my doctor before taking fondaparinux sodium injection?

Tell your doctor about all of your medical conditions, including if you:

- have had any bleeding problems (such as stomach ulcers)
- have had a stroke
- have had recent surgeries, including eye surgery
- have diabetic eye disease
- have kidney problems
- have uncontrolled high blood pressure
- are pregnant. It is not known if fondaparinux sodium injection will harm your unborn baby. If you are pregnant, talk to your doctor about the best way for you to prevent or treat blood clots.
- are breast-feeding. It is not known if fondaparinux sodium injection passes into breast milk.

Tell your doctor about all the medicines you take including prescriptions and non-prescription medicines, vitamins, and herbal supplements. Some medicines can increase your risk of bleeding. Especially tell your doctor if you take:

- aspirin
- NSAIDS (such as ibuprofen or naproxen)
- other blood thinner medicines, such as clopidogrel or warfarin

See **“What is the most important information I should know about fondaparinux sodium injection?”** Do not start taking any new medicines without first talking to your doctor.

Know the medicines you take. Tell all your doctors and dentist that you take fondaparinux sodium injection, especially if you need to have any kind of surgery or a dental procedure. Keep a list of your medicines and show it to all your doctors and pharmacist before you start a new medicine.

How should I take fondaparinux sodium injection?

- Take fondaparinux sodium injection exactly as prescribed by your doctor.
- Fondaparinux sodium is given by injection under the skin (subcutaneous injection). See **“How should I give an injection of fondaparinux sodium?”**
- If your doctor tells you that you may give yourself injections of fondaparinux sodium at home, you will be shown how to give the injections first before you do them on your own.

- Tell your doctor if you have any bleeding or bruising while taking fondaparinux sodium injection.
- If you miss a dose of fondaparinux sodium injection, take your dose as soon as you remember. Do not take 2 doses at the same time.
- If you take too much fondaparinux sodium injection, call your doctor right away.
- Do not use fondaparinux sodium injection if:
 - the solution appears discolored (the solution should normally appear clear),
 - you see any particles in the solution, or
 - the syringe is damaged.

What are possible side effects of fondaparinux sodium injection?

Fondaparinux sodium can cause serious side effects. See [“What is the most important information I should know about fondaparinux sodium injection?”](#)

- **Severe bleeding** Certain conditions can increase your risk for severe bleeding, including:
 - some bleeding problems
 - some gastrointestinal problems including ulcers
 - some types of strokes
 - uncontrolled high blood pressure
 - diabetic eye disease
 - soon after brain, spine, or eye surgery
- **Certain kidney problems can also increase your risk of bleeding with fondaparinux sodium injection.** Your doctor may check your kidney function while you are taking fondaparinux sodium injection.
- **People undergoing surgery who weigh less than 110 pounds.** See [“Who should not take fondaparinux sodium injection?”](#)
- **Low blood platelets.** Low blood platelets can happen when you take fondaparinux sodium injection. Platelets are blood cells that help your blood to clot normally. Your doctor may check your platelet counts while you take fondaparinux sodium injection. You may bruise or bleed more easily while taking fondaparinux sodium injection, and it may take longer than usual for bleeding to stop.

Tell your doctor if you have any of these signs or symptoms of bleeding while taking fondaparinux sodium injection.

- any bleeding
- bruising
- rash of dark red spots under the skin

- **Allergic reactions.** See [“What should I tell my doctor before taking fondaparinux sodium injection?”](#)

Other side effects include:

- **Injection site reactions.** Bleeding, rash, and itching can happen at the place where you inject fondaparinux sodium.
- **Low red blood cell counts (anemia).** Your doctor may check your red blood cell counts while you are taking fondaparinux sodium injection.

- **Increased liver enzyme test results.** Your doctor may check your liver function while you are taking fondaparinux sodium injection.
- **Sleep problems (insomnia).**

These are not all the possible side effects of fondaparinux sodium injection. Call your doctor if you have any side effects that bother you or don't go away.

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

How should I store fondaparinux sodium injection?

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

Safely, throw away fondaparinux sodium injection that is out of date or no longer needed.

Keep fondaparinux sodium injection and all medicines out of the reach of children.

General information about fondaparinux sodium injection

Medicines are sometimes prescribed for purposes other than those described in patient information leaflets. Do not use fondaparinux sodium injection for a condition for which it was not prescribed. Do not give fondaparinux sodium injection to other people. It may harm them.

This leaflet summarizes the most important information about fondaparinux sodium injection. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about fondaparinux sodium injection that is written for healthcare professionals. For more information about fondaparinux sodium injection, call 1-888-375-3784.

What are the ingredients in fondaparinux sodium injection?

Active Ingredient: fondaparinux sodium

Inactive Ingredients: sodium chloride and water for injection. Also contain hydrochloric acid and sodium hydroxide as pH adjusters

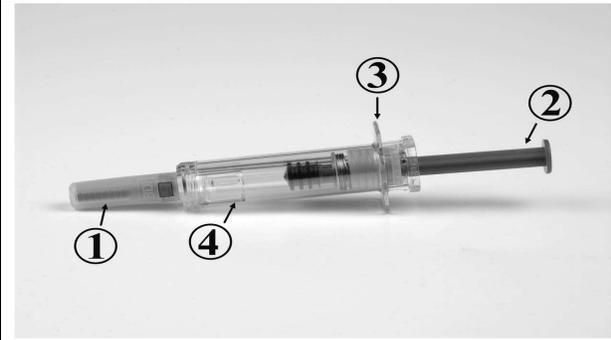
How should I give an injection of fondaparinux sodium?

Fondaparinux sodium is injected into a skin fold of the lower stomach area (abdomen). Do not inject fondaparinux sodium into muscle. Usually a doctor or nurse will give this injection to you. In some cases you may be taught how to do this yourself. **The following instructions are specific to the Preventis® injection system and may differ from the directions for other injection systems.** Be sure that you read, understand, and follow the step-by-step instructions in this leaflet, on how to give yourself an injection of fondaparinux sodium.

Instructions for self-administration

The different parts of fondaparinux sodium safety syringe are:

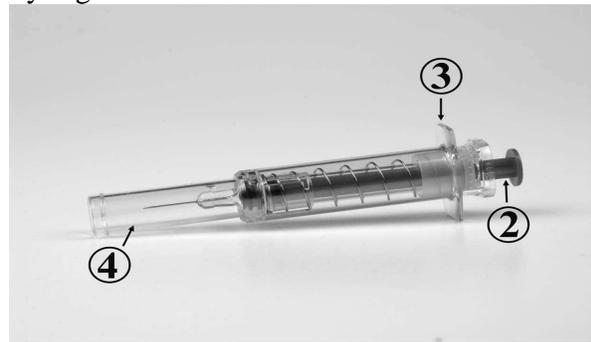
1. Rigid Needle Shield
2. Plunger
3. Finger-grip
4. Safety shield



Syringe BEFORE USE



Syringe AFTER USE



1. Wash your hands thoroughly with soap and water. Towel dry.
2. Sit or lie down in a comfortable position. Choose a spot on the lower stomach area (abdomen), at least 2 inches below your belly button (Figure A). Change (alternate) between using the left and right side of the lower abdomen for each injection. If you have any questions talk to your nurse or doctor.



Figure A.

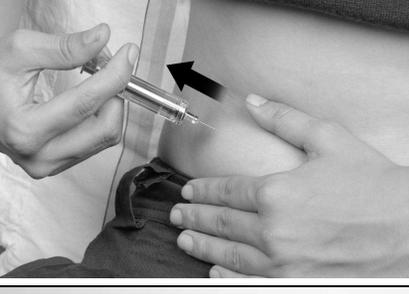
3. Clean the injection area with an alcohol swab.

4. Remove the needle shield by pulling it straight off the syringe (Figure B). Discard the needle shield.

To prevent infection, do not touch the needle or let it come in contact with any surface before the injection. A small air bubble in the syringe is normal. To be sure that you do not lose any medicine from the syringe, do not try to remove air bubbles from the syringe before giving the injection.



Figure B.

<p>5. Gently pinch the skin that has been cleaned to make a fold. Hold the fold between the thumb and the forefinger of one hand during the entire injection (Figure C).</p>		<p>Figure C.</p>
<p>6. Hold the syringe firmly in your other hand using the finger-grip. Insert the full length of the needle directly up and down (at an angle of 90°) into the skin fold (Figure D).</p>		<p>Figure D.</p>
<p>7. Inject all of the medicine in the syringe by pressing down on the plunger as far as it goes. (Figure E).</p>		<p>Figure E.</p>
<p>8. Remove the syringe from the injection site keeping your finger on the plunger.</p>		<p>Figure F.</p>
<p>9. Orient the needle away from you and others, and activate the safety shield by firmly pushing the plunger. The protective sleeve will automatically cover the needle and an audible "click" will be heard to confirm shield activation.</p>		<p>Figure G.</p>

Follow the instructions given to you by your nurse or doctor about the right way to throw away used syringes and needles. There may be state laws about the right way to dispose of used syringes, needles, and disposal containers.

NOTE:

- The safety system can only be activated once the syringe has been emptied.
- Activation of the safety system must be done only after removing the needle from the patient's skin.
- Do not replace the needle shield after injection.
- The safety system should not be sterilized.
- Activation of the safety system may cause minimal splatter of fluid. For optimal safety activate the system while orienting it downwards away from yourself and others.

To reorder additional Patient Information Sheets contact Dr. Reddy's Customer Service at 1-866-733-3952.

Rx Only

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