

SB 486 Safe Needle Disposal Plan

Submitted to:

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

December 2, 2011

Background

The State of California recently 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

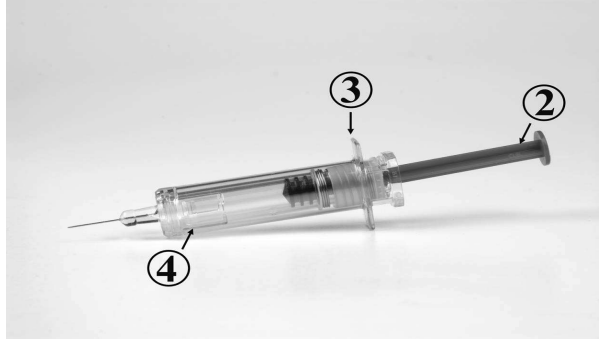
Subject To These Regulations In California

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

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.

Important Information about Fondaparinux Sodium Solution for Injection

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

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 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 (50 kg).**
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**.