

California Public Resources Code Sections 47115-47116:
Required Reporting by Pharmaceutical Manufacturer
Novo Nordisk Inc.

Novo Nordisk is a Danish based health care company and a world leader in diabetes care. Novo Nordisk's North American headquarters are located at 100 College Road West, Princeton, New Jersey, 08540. Novo Nordisk has approximately 1166 employees in Princeton and 2174 employees in the field.

Pursuant to the California Public Resources Code Sections 47115-47116, listed below are currently marketed Novo Nordisk products that utilize sharps and the steps we take to ensure safe disposal.

Our diabetes portfolio includes the following injectable products:

- Levemir® (insulin detemir [rDNA origin] injection)
- NovoLog® (insulin aspart [rDNA origin] injection)
- NovoLog® (insulin aspart [rDNA origin] injection) Mix 70/30
- Novolin® (regular, human insulin injection [recombinant DNA origin] USP)
- Victoza® (liraglutide [rDNA origin] injection)

Our delivery systems include (both diabetes and biopharmaceutical):

- FlexPen®
- GlucaGen® HypoKit®
- NovoFine® Needles
- NovoFine® Autocover® Needles
- NovoPen® 3
- NovoPen® Junior
- PenMate®
- FlexPro®

Our Biopharmaceutical portfolio includes the following injectable products:

- Norditropin®
- NovoSeven® RT®

Employee Disposal

All of our field personnel are trained on the safe disposal of products. Samples and/or devices that are expired or compromised are packaged and returned to Capital Returns Inc., located at 6101 North 64th Street, Milwaukee, Wisconsin, for destruction. Capital Returns is a certified medical waster disposal company that processes and destroys returned products.

Patient Returns

In the event a patient has an issue with a Novo Nordisk product, an 800 number is listed on our packaging for consumers to call for information and to report complaints. Patients who wish to return products due to defect can call that number and a customer service representative will register the complaint and then send a special shipping container to the patient. The patient subsequently returns the product to the Novo Nordisk manufacturing site in Clayton, North Carolina for investigation and subsequent destruction. Product that may require more detailed investigation is subsequently shipped to Denmark for additional analysis. A replacement product is then sent out to the patient. As per regulations, we inform the US Food and Drug Administration (FDA) of all patient reactions and certain product complaints, at minimum on an annual basis.

Patient Use and Education

Novo Nordisk provides hard copy and electronic educational materials for all of our sharp-using and sharp containing products. These materials include product inserts and product web pages (www.novonordisk-us.com). Proper use and disposal of sharps is covered in these materials.

We do not provide sharps containers for diabetes products nor do we supply funding to patients and/or other collection groups for the destruction of such materials. However, we do include a sharps container in the pediatric starter kit for Norditropin®. All of our material and literature are reviewed and approved internally, and sent to the FDA for review as per regulations. The material we provide on the use and disposal of sharps is comprehensive and simple to understand.

Diabetes

For patients using Novo Nordisk diabetes products we recommend the use of our NovoFine® and/or Autocover needles for all of our medication delivery systems. The patient literature supplied with these delivery systems illustrates the proper way to use and dispose of needles – that is to remove the cap and dispose of according to local and/or municipal regulations.

Biopharmaceuticals

NovoSeven® RT® is a product that is primarily administered in a clinical setting. Patients treated with NovoSeven® RT® under the FDA approved indication receive this product for:

- (1) Bleeding episodes in hemophiliacs with inhibitors to FVIII or FIX; and
- (2) In patients with acquired hemophilia and to prevent bleeds during surgical interventions or invasive procedures.

Materials related to administration of the product are disposed of according to the appropriate policies and procedures of the dosing institution for the destruction of biological waste.

Norditropin®, a product treating growth hormone deficiency, also uses a pen delivery system, in conjunction with our NovoFine® or Autocover needles. Educational materials and literature for this product illustrate the proper way to use and dispose of needles. For new pediatric patients using Norditropin®, our starter kit does include a sharps container for safe disposal of needles but no additional support is provided for disposition of needles, after receipt of the initial sharps container.