

Bayer HealthCare, LLC Sharps Disposal Submission to CalRecycle
Originally Effective July 1, 2010
Update Effective July 1, 2012

1. *“A pharmaceutical manufacturer that sells or distributes a medication in California that is usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device, shall, on or before July 1, 2010, and annually thereafter, submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of the waste devices.”*¹

Bayer HealthCare, LLC (“Bayer”) has two (2) products within its portfolio of prescription medications that are “usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device....” These include:

a. **BETASERON[®] (interferon beta-1b)**, which is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Betaseron[®] is given by injection under the skin (subcutaneous injection) every other day.

b. **KOGENATE[®] FS antihemophilic factor (recombinant)**, which is a recombinant factor VIII treatment indicated for the control and prevention of bleeding episodes and peri-operative management in adults and children (0-16 years) with hemophilia A. **Kogenate[®] FS** is also indicated for routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no preexisting joint damage.

Dosage and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding, and the patient’s clinical condition.² Careful control of replacement therapy is especially important in cases of major surgery or life threatening bleeding episodes.

It is recommended to use the IV administration set provided. A dose of Kogenate[®] FS may be administered over a period of 1 to 15 minutes. The rate of administration, however, should be adapted to the response of each individual patient. The pulse rate should be determined before and during administration of Kogenate[®] FS. If there is a significant increase in pulse rate, reducing the rate of administration or temporarily halting the injection allows the symptoms to disappear promptly.

¹ Excerpt, SB 486 (Chapter 591, Statutes of 2009). All statutory references are to this measure unless otherwise specified.

Bayer supports the safe collection and proper disposal of any used hypodermic needle, pen needle, intravenous needle, or any other similar device by several means, including among others as described below, clear instructions in each product's accompanying package insert and other product labeling.

2. *"The plan required...shall include, at a minimum, a description of the actions, if any, taken by the manufacturer to do the following,"*²

"(a) Provide for the safe collection and proper disposal of the waste devices."

i. As for **Betaseron®**:

Through Bayer's BETAPLUS™ patient support program, available to all Betaseron® patients, BETA Nurses are available to patients 24/7. Newly diagnosed patients or patients new to Betaseron® therapy are provided direct information by the BETA Nurses about proper disposal of used containers or needle clips to safeguard used sharps, through referral to designated sharps take-back locations, based upon the individual patient's area of residence.

In addition, many of Bayer's contracted specialty pharmacies which provide Betaseron also provide sharps containers or needle clips to safeguard used sharps.

Further, prescribing and patient information gives additional direction about proper sharps disposal:

Statement made in Patient Package Insert:

"Used needles and syringes may be placed in a container made specially for disposing of used syringes and needles (called a "Sharps" container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labeled "Used Syringes". Do not use glass or clear plastic containers. You should always check with your healthcare provider for instructions on how to properly dispose of used vials, needles and syringes. You should follow any special state or local laws regarding the proper disposal of needles and syringes.

DO NOT throw the needle or syringe in the household trash or recycle.

Always keep the disposal container out of the reach of children."

ii. As for **Kogenate® FS**.

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Kogenate® FS patients.

² Excerpt, SB 486

Further, prescribing and patient information gives additional direction about proper sharps disposal:

Section 2.4 "Instructions for Use":

Place needles in a sharps container after single use. Discard all equipment, including any reconstituted Kogenate® FS product, in an appropriate container.

Section 17 "Patient Counseling Information":

Dispose of all materials, including any leftover reconstituted Kogenate® FS product, in an appropriate container.

Terumo infusion set portion:

12. Dispose of used needles and materials following the policies and procedures of your facility, as well as federal and local regulations for "Sharps Disposal" (Fig. 6). (Note; Shows picture of a sharps container)

The Kogenate® FS vial-to-vial PI contains the following guidance statements:

Section 2.4 "Instructions for Use":

Place needles in a sharps container after single use. Discard all equipment, including any reconstituted Kogenate® FS product, in an appropriate container.

Section 17 "Patient Counseling Information":

Dispose of all materials, including any leftover reconstituted Kogenate® FS product, in an appropriate container.

BD Safety-Lok infusion set portion:

Dispose of all properly locked Safety-Lok™ Infusion Sets in appropriate container. Handle all biological samples and "sharps" (lancets, needles, administration sets, luer adapters, blood collection sets, etc.) in accordance with the policies and procedures of your facility. Discard all "sharps" in biohazard containers approved for their disposal.

"(b) Educate consumers about safe management and collection opportunities."

i. As for **Betaseron®**:

As described above, patient education is the focus of the BETAPLUS™ program, building upon the prescribing and patient information that gives additional

direction about proper sharps disposal:

Statement made in Patient Package Insert:

"Used needles and syringes may be placed in a container made specially for disposing of used syringes and needles (called a "Sharps" container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labeled "Used Syringes". Do not use glass or clear plastic containers. You should always check with your healthcare provider for instructions on how to properly dispose of used vials, needles and syringes. You should follow any special state or local laws regarding the proper disposal of needles and syringes.

DO NOT throw the needle or syringe in the household trash or recycle.

Always keep the disposal container out of the reach of children."

ii. As for **Kogenate® FS/Kogenate® FS w/ BIO-SET.**

In addition to the safe disposal services provided by Bayer's specialty provider network, several statements made in the package insert provide recommendations from Bayer for proper disposal of materials.

The Kogenate® FS with BIO-SET patient information package insert contains the following guidance statements:

Section 2.4 "Instructions for Use":

Place needles in a sharps container after single use. Discard all equipment, including any reconstituted Kogenate® FS product, in an appropriate container.

Section 17 "Patient Counseling Information":

Dispose of all materials, including any leftover reconstituted Kogenate® FS product, in an appropriate container.

Terumo infusion set portion:

12. Dispose of used needles and materials following the policies and procedures of your facility, as well as federal and local regulations for "Sharps Disposal" (Fig. 6). (Note; Shows picture of a sharps container)

The Kogenate® FS vial-to-vial PI contains the following guidance statements:

Section 2.4 "Instructions for Use":

Place needles in a sharps container after single use. Discard all equipment, including any reconstituted Kogenate® FS product, in an appropriate container.

Section 17 "Patient Counseling Information":

Dispose of all materials, including any leftover reconstituted Kogenate® FS product, in an appropriate container.

BD Safety-Lok infusion set portion:

Dispose of all properly locked Safety-Lok™ Infusion Sets in appropriate container. Handle all biological samples and "sharps" (lancets, needles, administration sets, luer adapters, blood collection sets, etc.) in accordance with the policies and procedures of your facility. Discard all "sharps" in biohazard containers approved for their disposal.

“(c) Support efforts by retailers, pharmaceutical distributors, manufacturers of injection devices, and other partners, including local governments, health care organizations, public health officers, solid waste service providers, and other groups with interest in protecting public health and safety through the safe collection and proper disposal of waste devices.”

i. As for **Betaseron®**:

Through Bayer's BETAPLUS™ patient support program, available to all Betaseron® patients, BETA Nurses are available to patients 24/7. Newly diagnosed patients or patients new to Betaseron® therapy are provided direct information by the BETA Nurses about proper disposal of used containers or needle clips to safeguard used sharps, through referral to designated sharps take-back locations, based upon the individual patient's area of residence. In addition, many of Bayer's contracted specialty pharmacies which provide Betaseron provide sharps containers or needle clips to safeguard used sharps.

ii. As for **Kogenate® FS**:

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Kogenate® FS patients.

iii. As to both products:

Bayer reinforces proper and appropriate disposal of home generated sharps in all injection training materials produced in conjunction with both products. These materials include, among several examples, product injection training videos, and injection training brochures and pamphlets.

Flexible and Safe Options for the safe disposal of home generated sharps have been identified by the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA). These guidelines offer a variety of disposal alternatives to accommodate geographic variability, patient preference and confidentiality, and local regulatory requirements. As a result of these numerous factors, the EPA and FDA have not identified a “one size fits all” recommendation for effective sharps management.

Agency Resources:

Food and Drug Administration:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm#whataresharps>

Environmental Protection Agency:

<http://www.epa.gov/osw/nonhaz/industrial/medical/med-govt.pdf>

3. (a) Posted on Bayer HealthCare, LLC website (www.pharma.bayer.com) and a copy of same is maintained at 6 West Belt, Wayne, NJ 07470-6806.

(b) The above was submitted on June 22, 2012, to the California Department of Resources, Recovery and Recycling (CalRecycle) in care of its designated e-mail contact, pharmasharps@calrecycle.ca.gov, with a copy to:

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