



HOUSEHOLD GENERATED SHARPS MANAGEMENT PLAN

Plan for Supporting the Safe Collection and Disposal of Waste
Devices for the Continental United States, Alaska, and Hawaii

July 2014

Introduction

AstraZeneca has prepared the following Household Generated Sharps Management Plan to support the safe collection and proper disposal of the sharps waste generated by patients using its products in the household setting. Under various state sanctioned regulations, pharmaceutical manufacturers that sell or distribute a medication that is self administered through the use of injectable devices have to prepare and/or submit to states a plan that describes how the manufacturer supports the safe collection and proper disposal of waste sharps. These regulations require the manufacturer to post and maintain their plans on their respective Internet web sites. Currently two states, California and Minnesota, have issued such requirements for Household Generated Sharps management. For California, the plan must be submitted to the California Integrated Waste Management Board and posted on the manufacturer's web site. The State of Minnesota only requires that the plan is posted on the manufacturer's web site.

Description of Sharps Disposal Program

For household sharp waste generated by prescribed self-injectable drugs administered at home, patients are provided with written information about proper use, collection and disposal of used syringes and injection pens in multiple forms, including: product welcome kits, educational materials, product Prescribing Information, Instructions for Use and Medication Guides, product websites, and individual patient support through diabetes educator sessions. Each of these resources provides information on proper use, collection and disposal of sharps, and directs patients to dispose of used sharps in a puncture resistant container.

The product Instructions for Use are easily accessible on each of the product-specific websites, as described below. The materials advise patients that there may be state and or local laws regarding the disposal of used sharps, and direct them to consult their local agency or health care provider to understand full compliance obligations in their specific location. Additionally, all brands have a patient assistance call center and trained educators available to provide this information.

Sharps Disposal Information Provided by AstraZeneca

In August of 2012, Bristol-Myers Squibb Company acquired Amylin Pharmaceuticals, LLC. The acquisition of Amylin Pharmaceuticals, LLC resulted in the expansion of the alliance between AstraZeneca and Bristol-Myers Squibb Company to incorporate the development and marketing of Amylin's portfolio of products: BYETTA® (exenatide), BYDUREON® (exenatide extended-release for injectable suspension), SYMLIN® (pramlintide acetate), and MYALEPT™ (metreleptin for injection). In February 2014, AstraZeneca acquired Bristol-Myers Squibb's interests in those products and now has the responsibility to comply with California's "Pharmaceutical Manufacturer Sharps Disposal Plans" annual reporting obligation. The AstraZeneca injectable products that generate this obligation include: BYETTA® (exenatide), BYDUREON® (exenatide extended-release for injectable suspension), SYMLIN® (pramlintide acetate), and MYALEPT™ (metreleptin for injection).

Patients prescribed an AstraZeneca injectable product receive Patient Prescribing Information, and Instructions For Use and/or a Medication Guide detailing the proper handling and disposal of waste sharps. Additionally, each product has information on its website as well as educational and support materials which provide patients with this information. Each product provides direction for proper storage and sharps disposal on its website, as follows:

BYDUREON®: <http://www.bydureon.com/getting-started/how-to-store-it>

BYETTA®: <http://www.byetta.com/getting-started-on-byetta/storage-and-disposal-information>

SYMLIN®: <http://www.symlin.com/throwaway.htm>

MYALEPT: http://www1.astrazeneca-us.com/pi/ifu_myalept.pdf#page=1

BYETTA® (exenatide) injection –

How do I throw away my needles?

- Do not throw away the pen with a needle attached.
- Place used needles in a closeable, puncture-resistant container. You may use a sharps container (such as a red biohazard container), a hard plastic container (such as a detergent bottle), or a metal container (such as an empty coffee can). Ask your healthcare provider for instructions on the right way to throw away (dispose of) your used pens and the container. There may be state and local laws about how you should throw away used pens and needles.
- Do not throw the disposal container in the household trash. Do not recycle.

- Always keep the puncture-proof container out of reach of children.

- **Never share your BYETTA Pen or needles with another person. You may give an infection to them, or get an infection from them, and BYETTA may harm them.**
- Be sure to read the [User Manual](#) that comes with your BYETTA Pen for more complete instructions.

<http://www.byetta.com/getting-started-on-byetta/storage-and-disposal-information>

BYDUREON® (exenatide extended-release for injectable suspension)

Proper disposal of needles is important for your safety and the safety of those around you.



- Use a biohazard container made specifically for disposing of used syringes (called a "sharps" container) or a puncture-resistant container to throw out the syringe with the needle still attached. To avoid a needlestick injury, do not put the cover back on the needle.
- Throw away all other parts in the trash. You do not have to save them.
- Each single-dose tray has a new supply of parts to use for your weekly dose of BYDUREON.
- Check with your healthcare provider or pharmacist for instructions about the right way to dispose of used syringes. There may be special local or state laws about how to dispose of used syringes and/or puncture-resistant containers.

<http://www.bydureon.com/getting-started/how-to-store-it>

SYMLIN® (pramlintide acetate) pen-injector

How do I throw away used pen-injectors and needles?

Check with your healthcare provider or pharmacist for instructions about the correct way to throw away used pen-injectors and needles. There may be special local or state laws about how to throw away used pen-injectors and needles. Follow local or institutional policies regarding needle handling and disposal.

- Throw away used needles in a puncture-resistant container or as directed by your healthcare provider. Do not throw away the Pen with a needle attached. Do not throw away used pen injectors and needles in the household trash and do not recycle them.
- Put used and empty SymlinPen® (pramlintide acetate) pen-injector in a biohazard container made specifically for disposing of used needles (called a "sharps" container) or in a hard plastic container with a screw-on cap (such as an empty detergent bottle) or in a metal container with a plastic lid (such

as a coffee can). Sharps containers can be purchased at your local pharmacy or many retail outlets.

- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off.
- Keep SymlinPen® (pramlintide acetate) pen-injector and the disposal container out of the reach of children.

<http://www.symmlin.com/throwaway.htm>

MYALEPT™ (metreleptin for injection)

Myalept was recently approved (February 2014) and therefore its patient education materials and website are under construction. In the meantime, the Patient Prescribing Information and provided with each prescription includes the Instructions for Use which provides direction for proper disposal of sharps, as follows:

Disposing of Used Needles and Syringes:

- Put your used needles and syringes in a FDA- cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - Made of heavy-duty plastic
 - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - Upright and stable during use
 - Leak-resistant, and
 - Properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

http://www1.astrazeneca-us.com/pi/ifu_myalept.pdf#page=1

AstraZeneca's Household Generated Sharps Management Plan and some related reference guidance is available at the following Internet web site:

<http://www.astrazeneca-us.com/responsibility/corporate-transparency/us-compliance-program>

Additional Sharps disposal guidance for all states is available at the following web pages:

<http://www.safeneedledisposal.org/>

<http://www.epa.gov/wastes/wyl/stateprograms.htm>

<http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm>