



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 2019

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 using injectable devices must 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 Department of Resources, Recycling and Recovery (CalRecycle) and be 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.

The AstraZeneca injectable products that generate this obligation include: BYETTA® (exenatide), BYDUREON® Pen (exenatide extended-release for injectable suspension), BYDUREON BCise (exenatide extended-release) injectable suspension, BYDUREON® Single-Dose Tray (exenatide extended release for injectable suspension), and SYMLIN® (pramlintide acetate).

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® Pen:

https://www.azpicentral.com/bydureon/ifu_bydureon.pdf#page=1

BYDUREON BCise:

https://www.azpicentral.com/bydureon_bcise/bydureon_bcise_ifu.pdf#page=1

BYDUREON® Single-Dose Tray:

https://www.azpicentral.com/bydureon/ifu_bydureon.pdf#page=1

BYETTA®:

https://www.azpicentral.com/byetta/byetta_ifu.pdf#page=1

SYMLIN®:

<https://www.symlin.com/using-symlin/how-to-use-symlin.html>

BYDUREON® Pen (exenatide extended-release for injectable suspension)



Properly dispose of your Pen.

- Put your used needles and Pens in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens in your household trash. See Common Questions and Answers for additional disposal information

What if I do not have an FDA-cleared sharps disposal container?

Do not throw away (dispose of) loose needles and Pens in your household trash.

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a 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 sharp's disposal container. There may be state or local laws about how you should throw away used needles and Pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>

https://www.azpicentral.com/bydureon/ifu_bydureon.pdf#page=1

BYDUREON BCise (Exenatide extended-release) injectable suspension



C. Disposal.

Put your used autoinjector in a FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) loose needles and syringes into your household trash. If you do not have an 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 that will not let sharps 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 that you live in, go to FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container. See "Common Questions and Answers" for additional disposal information.

Please keep these instructions to use for your next dose.

https://www.azpicentral.com/bydureon_bcise/bydureon_bcise_ifu.pdf#page=1

suspension) Adapted from BYDUREON

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



Disposing of used Needles and Syringes:

- Put your used needles and syringes in an 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 an FDA-cleared sharps disposal container, you may use a household container that is:
 - o made of a heavy-duty plastic,
 - o can be closed with a tightfitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak-resistant, and
 - o 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 pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

https://www.azpicentral.com/bydureon/ifu_bydureon.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.

https://www.azpicentral.com/byetta/byetta_med.pdf#page=1

SYMLIN® (pramlintide acetate) pen-injector

After your injection:

- Put your used needles and Symlin Pen in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash. o If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a 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 sharp's disposal container. There may be state or local laws about how you should throw away used needles and SymlinPen. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

<https://www.symlin.com/using-symlin/how-to-use-symlin.html>

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

<https://www.astrazeneca-us.com/household-generated-sharps-management-plan.html>

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

<http://safeneedledisposal.org>