



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 2021

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 BCise® (exenatide extended-release) injectable suspension, SYMLIN® (pramlintide acetate) and FASENRA Pen® (benralizumab) for Subcutaneous Injection Single Dose Auto Injector.

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 BCise®:

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

BYETTA®:

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

SYMLIN®:

<http://www.azpicentral.com/pi.html?product=symmlinpen60&ifu=y>

FASENRA PEN®

<https://www.azpicentral.com/fasenra/fasenra.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

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

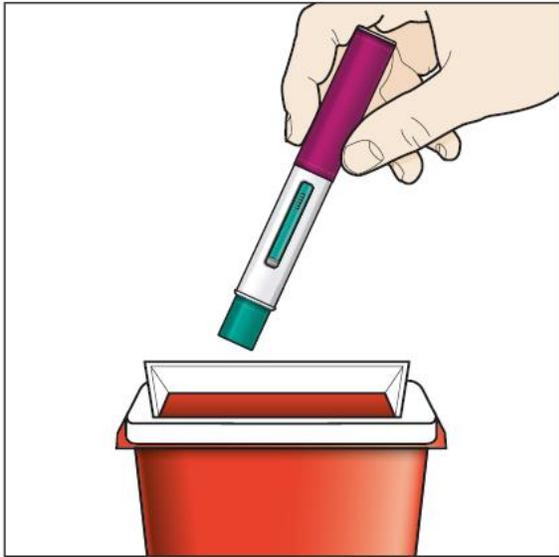
- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid,
- without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost 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 Symlin Pen. 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.

<http://www.azpicentral.com/pi.html?product=symlinpen60&ifu=y>

FASENRA Pen® (benralizumab) Single Dose Auto Injector

Dispose of the used FASENRA Pen safely



- Each FASENRA PEN contains a single dose of FASENRA and **cannot be reused**.
- Put your used FASENRA PEN in a FDA-cleared **sharps disposal container** right away after use.

Do not throw away the FASENRA PEN in your household trash.

Throw away the cap and other used supplies in your household trash.

Disposal guidelines

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

- made of a heavy-duty plastic,
- can be used 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 for the area 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.

For more information go to www.FasenraPen.com or call 1-800-236-9933. If you still have questions, call your healthcare provider.

<https://www.azpicentral.com/fasenra/fasenra.pdf#page=1>

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>