

Promius Pharma

A Subsidiary of Dr. Reddy's Laboratories, Inc.

SB 486 Safe Needle Disposal Plan

**Department of Resources Recycling and Recovery
(CalRecycle)**

01 July 2018 (2019 - Updated for CA Compliance)

Background

The State of California has enacted two laws to address home generated sharps disposal. The first law (SB 1305), makes it illegal for any person in the state of California to dispose of home generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container. This law became effective September 1, 2008. In 2009, California enacted (SB 486) which requires any pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste devices. This plan is due on July 1, 2010 and annually thereafter.

Promius Pharma Self-Injectable Products Subject To These Regulations in California

Promius Pharma currently markets, distributes, and/or sells one self-injectable product in the State of California. The name of this product is **ZEMBRACE[™] SymTouch[™] (sumatriptan injection) 3 mg/0.5 mL**.

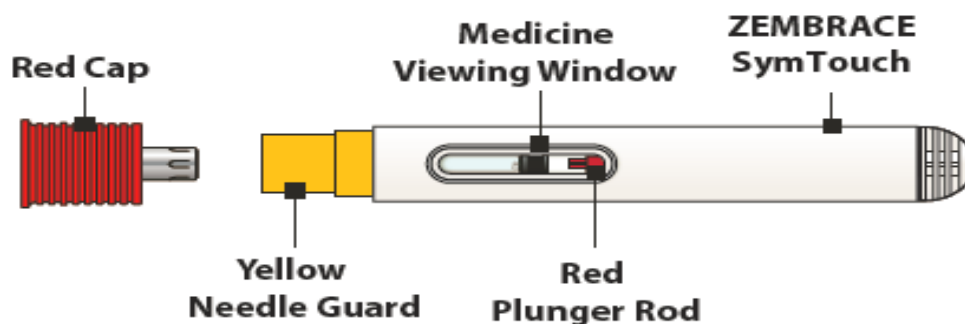
Promius Pharma supports safe collection and proper disposal of home generated sharps

Promius Pharma supports appropriate and safe disposal of home-generated waste sharps. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed.

During the development of ZEMBRACE[™] SymTouch[™] (sumatriptan injection) 3 mg/0.5 mL Promius Pharma employed safe needle technology in order to protect patients and those assisting in the disposal of waste sharps. Specifically, ZEMBRACE[™] SymTouch[™] (sumatriptan injection) 3 mg/0.5 mL uses a 29 gauge needle that is 0.5mm (1/4 inch) long and has a needle shield which covers the needle and locks after the injection. The patient is then instructed to recap the device for disposal. The steps for use of the auto-injector are described in the ZEMBRACE[™] SymTouch[™] (sumatriptan injection) 3 mg/0.5 mL Patient Information and Instructions for Use (IFU) leaflets.

ZEMBRACE[™] SymTouch[™] (sumatriptan injection) 3 mg/0.5 mL

The parts of the auto-injector are shown in this picture





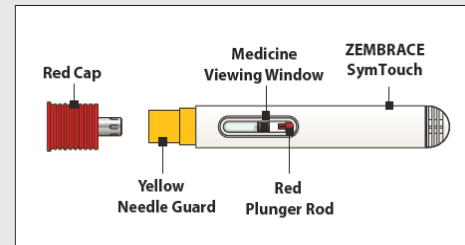
Instructions for Use | ZEMBRACE™ SymTouch™ (Zem-brace Sim-Touch) (sumatriptan succinate) Injection

Read this Instructions for Use before you start to use ZEMBRACE™ SymTouch™. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. You and your healthcare provider should talk about ZEMBRACE SymTouch when you start taking it and at regular checkups.

The ZEMBRACE SymTouch Autoinjector is a single-use, pre-filled injection device with the exact dose you need. The device should be used only 1 time and then discarded.

⚠ Important Precautions

Keep out of reach of children.
Do not use after the expiration date has passed.
Do not store or expose to high temperatures.
Do not freeze.
Do not remove the Red Cap until you are ready to inject.
Do not use if dropped after removing the Red Cap.
Do not put or press thumb, fingers or hand over the Yellow Needle Guard.



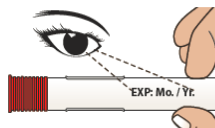
Step 1 - Inspect Autoinjector and Gather Supplies

► 1A - Remove Autoinjector from the carton

► 1B - Check the Expiration Date on the Autoinjector

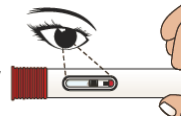
► 1C - Inspect the medicine through the Medicine Viewing Window

► 1D - Gather the following supplies

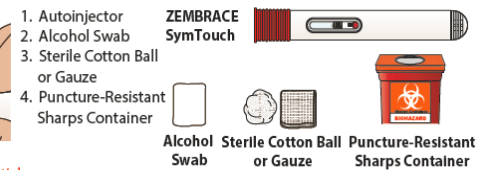


Do not use if the expiration date has passed.

Inspect the appearance of ZEMBRACE SymTouch Autoinjector medicine through the medicine window. It must be a clear, colorless to pale yellow solution.



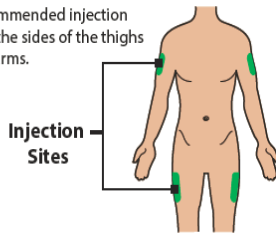
Do not inject the medicine if the solution looks discolored or cloudy or contains lumps, flakes, or particles.



Step 2 - Choose and Prepare Your Injection Site

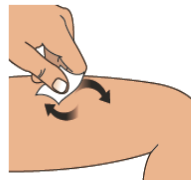
► 2A - Choose your injection site

The recommended injection sites are the sides of the thighs and the arms.



Caution: Do not inject where your skin is scarred, bruised, tender, red or near any open wound.

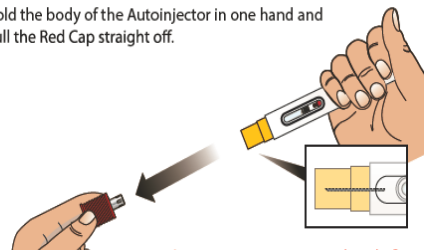
► 2B - Clean the injection site with an alcohol swab



Do not touch injection site area after cleaning.

► 2C - Remove the Red Cap

Hold the body of the Autoinjector in one hand and pull the Red Cap straight off.



Warning: Do not put or press thumb, fingers or hand over the Yellow Needle Guard, doing so may result in a needle stick injury.

Step 3 - Inject the Medicine

► 3A - Place Autoinjector straight on your injection site

Place the Autoinjector straight on your injection site (90 degrees) with the Yellow Needle Guard end gently pressed against your skin.



► 3B - Perform Injection

Press and hold the Autoinjector down against your skin. You will hear the first "Click 1" as the injection starts. Continue to hold the device down until you hear the second "Click 2."

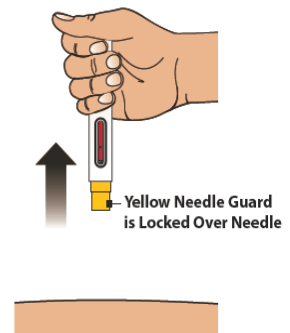
Wait 5 seconds before you remove the Autoinjector!



CONTINUE TO HOLD DOWN AND SLOWLY COUNT TO 5.
⌚ 1...2...3...4...5

► 3C - Remove Autoinjector from skin

Remove the Autoinjector by lifting it straight away from your skin. The Yellow Needle Guard will drop down and lock over the needle.

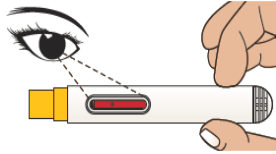


Important: To receive your full dose, always hold the Autoinjector down on your injection site for additional time after you hear the second click. This allows all of the medicine to be delivered.

Step 4 - Confirm Injection and Dispose the Autoinjector

► 4A - Confirm Red Color in Medicine Viewing Window

Look to confirm that the Red Plunger Rod has filled the Medicine Viewing Window. This means you received the full dose.



Caution: Call your healthcare provider if the Red Plunger Rod has not filled the Medicine Viewing Window. This may mean that only a partial dose was delivered.

Do not try to reuse the Autoinjector.

► 4B - Disposal of the Autoinjector

Put your used Autoinjector, caps, needles, and sharps 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. Do not recycle your used sharps disposal container.

If you do not have a 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 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 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.

If needed, make sure you get a refill of your Autoinjector.



► 4C - Treat Injection Site

Treat the injection site with a cotton ball, gauze pad or bandage, as needed.

Do not rub the injection site.

ZEMBRACE SymTouch are registered trademarks of Dr. Reddy's Laboratories, Ltd.

PROMIUS[®]
PHARMA

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Month Year

Patient Education Materials:

Patients who self-inject Promius Pharma products at home should receive instructions from their healthcare providers on how to use these products properly. The full prescribing information is available to healthcare providers. Patients should read the Patient Information and the Instructions for Use (IFU) leaflets that come with each product before they start taking each product and each time the prescription is refilled as there may be new information.

Promius Pharma has also created a patient specific website for ZEMBRACE[™] SymTouch[™] (sumatriptan injection) 3 mg/0.5 mL at www.zembrace.com. This website provides patients with the most important information they need to know from Promius Pharma. The information on this website does not take the place of talking with the patient's healthcare provider about the medical conditions or treatments.

Patients and caregivers can also contact Promius Pharma at 1-888-966-8766 with questions about this product.

Disposal:

Patients and consumers have several options available to them to safely dispose sharps waste. Patients may visit the CalRecycle website <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm> to become familiar with all disposal options available and select the option that is most convenient. Below are disposal options detailed on the California CalRecycle website.

- Patients may use the Disposal Directory (FacIT) for Sharps and Medication (via link <http://www.calrecycle.ca.gov/facit/facility/search.aspx>). In this directory, you may locate facilities that collect sharps for disposal near to where you live or work. Collection programs include:
 - **Pharmacies.** Some drug stores take back their customers' needles, especially in small quantities.
 - **Hospitals.** Hospitals may take back sharps from patients using regular outpatient services.
 - **Local Household Hazardous Waste Programs.** Call your local household hazardous waste agency and ask if they collect needles (sharps) at their collection facilities or on household hazardous waste days. You can also look for this information here:
 - Your local white pages' government section may list your city's or county's household hazardous waste department.

- Visit the <http://www.earth911.com/recycling-guide/how-to-recycle-medical-sharps/> website or call 1-800-CLEANUP (1-800-253-2687), a service of Earth 911.
- **Local Jurisdiction Sharps Collection Programs.** A file showing a sampling of local jurisdictions' sharps collection programs containing contacts, e-mail addresses, program summaries, and outreach materials may be found at <http://www.calrecycle.ca.gov/homehazwaste/sharps/LocalProgram.pdf> this spreadsheet could help jurisdictions that don't currently have collection programs to set up their own sharps collection program.
- **Needle Destruction Devices.** The U.S. Food and Drug Administration (FDA) currently only lists the "Disintegrator" as a needle destruction device approved for use by self-injectors.
- **Mail-Back Service.** A list of sharps waste mail-back services authorized for use in California is available from the California Department of Public Health (CDPH) is available at <https://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/SharpsMailBackList.pdf>
- **Sharps Containers.** The California Department of Public Health Medical Waste Management Program is recommending the use of sharps containers approved by the FDA. After accessing the FDA website www.fda.gov, type "sharps" in the search box. The container names will display alphabetically.

For More Information

Stay informed about the latest developments in CalRecycle's efforts to promote safe disposal of sharps waste.

- **Listserv:** To receive periodic information about sharps, subscribe to the Sharps and Medication Disposal Listserv at <http://www.calrecycle.ca.gov/listservs/Subscribe.aspx?ListID=73>
- **Contact:** Please contact <http://www.calrecycle.ca.gov/homehazwaste/sharps/> for questions or more information.

Company Contact Information:

If you would like assistance from Promius Pharma in identifying your disposal options, please contact a Promius Pharma representative at 1-888-966-8766. Representatives are available to assist patients with questions about each of these products, including product administration and medical waste disposal.

Promius Pharma remains committed to help facilitate the safe disposal of its products and will continue to evaluate feedback and make modifications to this plan as needed.