



SB 486 Safe Needle Disposal Plan

Submitted to:

Department of Resources Recycling and Recovery (CalRecycle)

July 1, 2011

Background:

The State of California recently 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.

GSK Self-Injectable Products Subject To These Regulations In California

GSK currently markets, distributes, and/or sells two self-injectable products in the State of California. The brand names of these products are Imitrex® (sumatriptan succinate) Injection and ARIXTRA® (fondaparinux sodium) Injection.

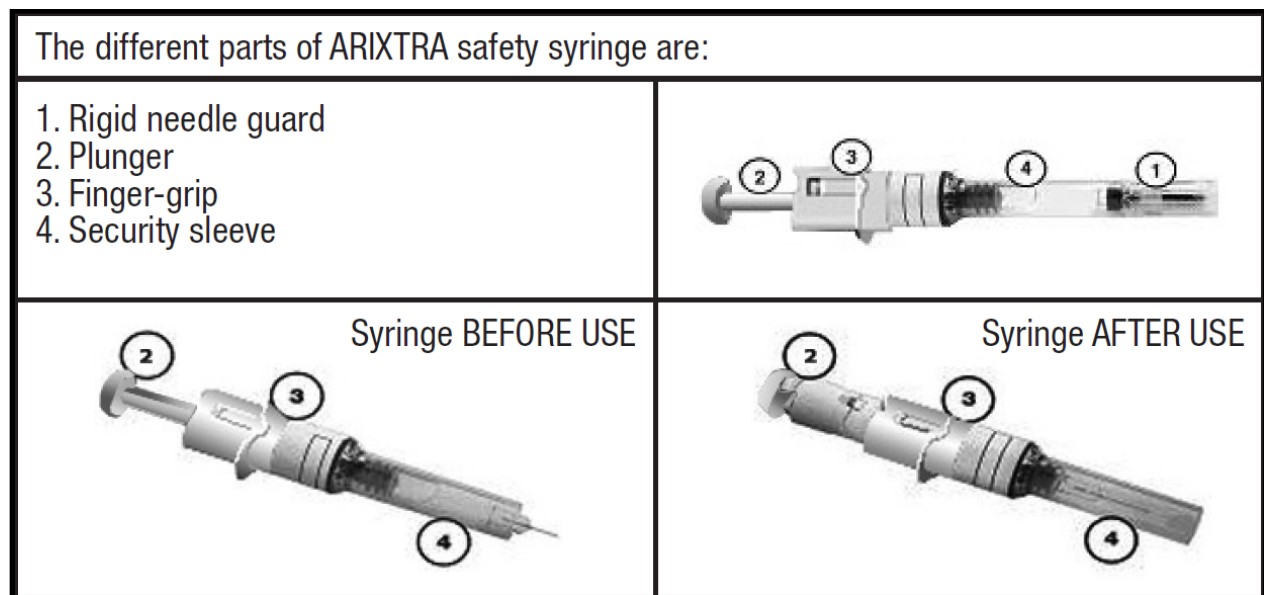
ARIXTRA® is indicated for the prevention of blood clots after hip fracture, hip or knee replacement surgery or in certain patients after abdominal surgery. This medication is also indicated for the treatment of blood clots. The usual duration of administration of ARIXTRA® is five to nine days.

Imitrex® is indicated for the acute treatment of migraine attacks. There are 2 basic types of migraine-specific therapies — acute and preventative. Acute medications are designed to relieve a migraine after it starts, and preventative medications are designed to help eliminate or significantly reduce the frequency of a person's migraines. Imitrex® Injection is indicated for 1) the acute treatment of migraine attacks with or without aura in adults and 2) the acute treatment of cluster headache episodes in adults. Patients are instructed to administer via injection this medication in accordance with the instruction of a physician or other suitably qualified health care professional.

GSK Supports Safe Collection and Proper Disposal of Home Generated Sharps

GSK has demonstrated a strong commitment to the safe and proper use and disposal of its self-injectable medications. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed. In fact, inherent in the design of both products, GSK used safe needle technology to shield the sharps and provides, at a minimum, approved sharps containers for home generated sharps waste materials.

Specifically, ARIXTRA® uses a 27 gauge needle that is only a half-inch long and the automatic needle protection system retracts the needle once medication is dispensed.



Starter kits, including the Prescribing Information for ARIXTRA®, and an approved sharps container and information leaflet, are offered to Patients via healthcare practitioners.

Additional disposal instructions (including California specific requirements), are provided through the GSK Customer Care Call Center.



Imitrex® Injection is available in the easy-to-use Imitrex® STATdose System, which allows patients to conveniently administer Imitrex with just the push of a button.

The Imitrex® STATdose System includes two small, disposable cartridges pre-filled with a single dose of Imitrex®, and an easy to use autoinjector pen that allows patients to self-administer the medication about one-quarter inch under the skin. With the Imitrex® STATdose System, patients can treat migraines quickly and conveniently while avoiding direct contact with a needle or syringe. After injection, the used sharp is placed into the empty cartridge. The California Department of Health, Medical Waste Management Office has designated the empty cartridge as an approved sharps container that is suitable for transportation to an approved collection facility. Disposal instructions (including California specific requirements), are provided through the GSK Customer Care Call Center.



In summary, GlaxoSmithKline supports the safe collection and proper disposal of home generated sharps by providing at no cost to the patient, appropriate sharps disposal containers and educational materials on proper sharps disposal. Patients may contact our Toll Free Customer Call Center Hotline to obtain California specific disposal information including the locations of sharps collection facilities near their homes where they can dispose of their sharps free of charge.