

FACT SHEET FOR PATIENTS AND CAREGIVERS:

Use of the Rafa Atropine Auto-Injector for Initial Treatment of Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning

You are being given the Rafa Atropine Auto-Injector because you or someone you know may have been exposed to nerve agents or certain insecticides (organophosphorus and/or carbamate) that could cause injury, harm, or death. These nerve agents or insecticides attack the central nervous system, the part of your body that controls your brain, spinal cord, and nerves. These nerve agents or insecticides can be a liquid, gas, or solid. As little as one drop of some nerve agents on your skin can cause death within 15 minutes of contact.

Atropine is used as the initial treatment for symptoms of nerve agent or certain insecticide poisoning. The Rafa Atropine Auto-Injector, which contains atropine, is being made available to treat poisoning by nerve agents or certain insecticides (organophosphorus and/or carbamate). This medicine may increase your chance of survival after coming in contact with these nerve agents or certain insecticides.

This Fact Sheet contains:

- A. Information to help you understand the risks and benefits of the Rafa Atropine Auto-Injector you have received or may receive.
- B. Instructions on how you or a caregiver can give (administer) the Rafa Atropine Auto-Injector in an emergency if a healthcare provider is not available to administer it.

A. INFORMATION ABOUT THE RISKS AND BENEFITS OF THE RAFA ATROPINE AUTO-INJECTOR

What is atropine and what is the Rafa Atropine Auto-Injector?

Atropine is a medicine to help reduce or block the effects of nerve agent or certain insecticide poisoning (organophosphorus and/or carbamate). This medicine comes in a self-containing device (auto-injector) which gives only a single dose by injection (shot) into the outer thigh. The needle that springs out of the device to deliver a single dose cannot be drawn back and the device cannot be reused. Each injector called the Rafa Atropine Auto-Injector is made to self-administer or administer the medicine to another person. The Rafa Atropine Auto-Injector is available in three doses that are administered based on a person's weight or age: 0.5 mg, 1 mg, or 2 mg. The different auto-injector doses are color-coded, as shown below. **See Table 1 for selecting the correct dose based on a person's weight (or age if the weight is not known).**



Who can receive the Rafa Atropine Auto-Injector?

The Rafa Atropine Auto-Injector should be administered only to adults and children weighing 15 lbs [7 kg] or more (generally 6 months of age and older) who have been exposed to nerve agents or certain insecticides and are experiencing symptoms of nerve agent or insecticide poisoning. **See Table 2 below for symptoms of nerve agent or insecticide poisoning.**

What are the symptoms of nerve agent or insecticide poisoning?

Symptoms of nerve agent or insecticide poisoning may include nausea, vomiting, stomach cramps, inability to control urine and/or stool, confusion, muscle twitching or weakness, and convulsions (seizures). The number of Rafa Atropine Auto-Injectors needed depends on how **mild** or **severe** the symptoms are. **See Table 2 below for mild or severe symptoms of nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning.**

What are the risks or side effects of the Rafa Atropine Auto-Injector?

The person who receives the injection may feel pain at the injection site. The serious and most common side effects of the Rafa Atropine Auto-Injector can include the following:

- Dry mouth
- Headache
- Nausea
- Vomiting
- Fast heartbeat or pounding in your chest (palpitations)
- Blurred vision
- Sensitivity to light
- Constipation
- Skin or cheeks get red (flushing)
- Feels like your stomach is swelling (abdominal distention)
- Dizziness
- Confusion
- Difficulty urinating
- Inability to urinate

If possible, consult your healthcare provider if any of these side effects occur.

Can the Rafa Atropine Auto-Injector be given to pregnant women or women who are breastfeeding?

It is not known if atropine can harm an unborn baby when given to a pregnant woman. Small amounts of atropine have been found in human milk. The benefit of atropine treatment in known or suspected exposure of nerve agent or certain insecticide poisoning may outweigh the risks.

What if I decide not to receive the Rafa Atropine Auto-Injector?

It is your choice whether or not to receive the Rafa Atropine Auto-Injector. However, it is possible that the Rafa Atropine Auto-Injector may be given to you in a life-threatening situation where you are not able to make a decision or provide consent. Poisoning by nerve agents or certain insecticides is a serious and potentially deadly illness that can occur very fast after exposure; atropine is a known antidote for such poisoning. If you decide not to be treated after exposure, the chance of dying is greater. There is still a chance of getting sick or dying even with atropine treatment, if not administered quickly or dosed correctly.

Is the Rafa Atropine Auto-Injector approved by the Food and Drug Administration (FDA)?

The Rafa Atropine Auto-Injector is not an FDA-approved product. FDA has authorized the use of the Rafa Atropine Auto-Injector under an Emergency Use Authorization (EUA) because of the lack of available FDA-approved atropine auto-injectors made by other manufacturers.

An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The Secretary of the U.S. Department of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of injectable treatments for nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning, such as the Rafa Atropine Auto-Injector, under an EUA. FDA authorized the emergency use of the Rafa Atropine Auto-Injector to treat nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning only for the duration of the threat of the emergency, unless the EUA is terminated or revoked by FDA sooner.

B. INSTRUCTIONS FOR ADMINISTERING THE RAFA ATROPINE AUTO-INJECTOR

If possible, a healthcare provider or someone who has been trained to identify and treat the symptoms of exposure to nerve agents or insecticides should administer the Rafa Atropine Auto-Injector. However, if a healthcare provider is not available during an emergency, you or a caregiver might need to administer the Rafa Atropine Auto-Injector.

Which dose of Rafa Atropine Auto-Injector do I administer to myself or others?

The dose a person receives should be based on their weight or their age. Use **Table 1** below to determine the correct dose. Remember, do **NOT** use Rafa Atropine Auto-Injectors in a child weighing less than 15 lbs [7 kg] (generally younger than 6 months of age).

Note: It is important that you use only the dose recommended for a person's weight or age; do not attempt to use an auto-injector other than the dose recommended in **Table 1**. Once activated, the auto-injector delivers the full dose; partial doses are not possible.

Table 1. Rafa Atropine Auto-Injector Dose by Weight or Age

Weight (or age if weight unknown)	Atropine Dose
Children weighing 15 lbs to 40 lbs (7 kg to 18.4 kg) (generally 6 months to 4 years of age)	 0.5 mg Atropine Auto-Injector (Blue label)
Children weighing 41 lbs to 90 lbs (18.5 kg to 41 kg) (generally 5 years to 10 years of age)	 1 mg Atropine Auto-Injector (Red label)
Adults and children weighing over 90 lbs (over 41 kg) (generally over 10 years of age)	 2 mg Atropine Auto-Injector (Green label)

How many Rafa Atropine Auto-Injectors do I administer to myself or others?

The number of Rafa Atropine Auto-Injectors to administer should be based on symptoms.

- If you or another person has **2 or more MILD** symptoms listed in **Table 2**, follow the instructions under the **Mild Symptoms** section below (and see **Figure 1**).
- If you or another person has **any SEVERE** symptoms listed in **Table 2**, follow the instructions listed under the **Severe Symptoms** section below (and see **Figure 1**).

MILD SYMPTOMS (see Table 2)

First Dose: If you have or see someone who has **2 or more mild symptoms** listed in **Table 2** and exposure is known or suspected, **give one (1)** injection of atropine into the outer thigh using the Rafa Atropine Auto-Injector. *You can inject through clothing, but make sure pockets at the injection site are empty.* Keep checking to see if symptoms are continuing or getting worse. Seek medical help right away.

Additional Doses: Wait 10 minutes after giving the first dose (1 injection) for the medicine to work. If after the first dose (1 injection) the person who was exposed starts to show any of the severe symptoms listed in **Table 2**, you will need to **give two (2) more** injections to the person using a **new auto-injector for each injection**, quickly one right after the other. **Do not** use the same auto-injector more than once. **If possible, someone other than the affected person should give the second and third injections.** *You can give additional doses through clothing, but make sure pockets at the injection site are empty.*

SEVERE SYMPTOMS (see Table 2)

If you have or see someone with any of the **severe** symptoms listed in **Table 2** and exposure is known or suspected, or you see an exposed person passed out (unconscious), immediately **give three (3)** injections, using three separate auto-injectors. The auto-injectors should be given quickly into the outer thigh, one right after the other. *You can inject through clothing, but make sure pockets at the injection site are empty.* Get medical help right away.

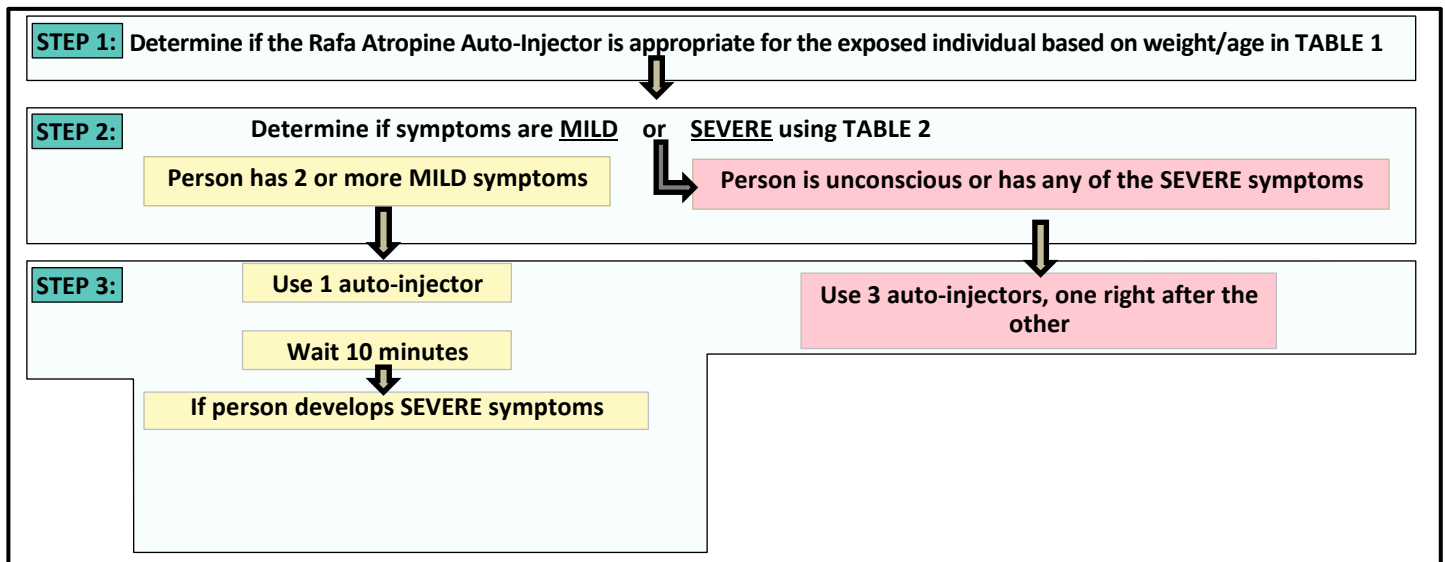
Table 2. Symptoms of nerve agent or insecticide poisoning

<p><u>MILD symptoms include:</u></p> <ul style="list-style-type: none"> • Blurred vision or small pupils • Unexplained excessive teary eyes* • Unexplained excessive runny nose* • Increased saliva or drooling* • Chest tightness, difficulty breathing, wheezing, or coughing • Shaking (tremors) throughout the body or muscle twitching • Nausea, vomiting, stomach cramps, or diarrhea • Fast heartbeat or pounding in your chest (tachycardia) or slow heartbeat (bradycardia) 	<p><u>SEVERE symptoms include:</u></p> <ul style="list-style-type: none"> • Strange or confused behavior • Passing out (unconsciousness) • Severe problems with breathing and/or gasping, shortness of breath (air hunger) • Large amount of fluid (secretions) coming from the mouth or nose • Severe muscle twitching, general weakness, or paralysis** • Inability to control urine and/or stool (bowel movement) * • Sudden violent or irregular movements of parts of your body (convulsions or seizures)
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Symptoms in infants and children:

* These symptoms are sometimes seen in infants and young children who do not have nerve agent or insecticide poisoning and are less reliable than other symptoms listed to determine poisoning. Symptoms should be considered collectively when nerve agent or insecticide exposure is known or suspected.
 **Infants may become sleepy, unconscious, or have muscle floppiness rather than muscle twitching after exposure to nerve agents or certain insecticides.

Figure 1. Summary of steps for determining number of Rafa Atropine Auto-Injector(s) to administer


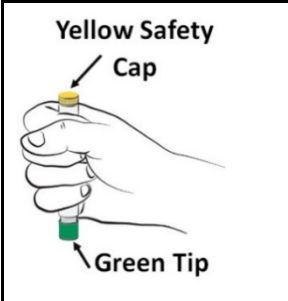
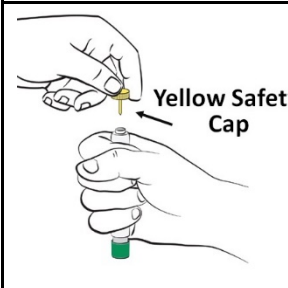
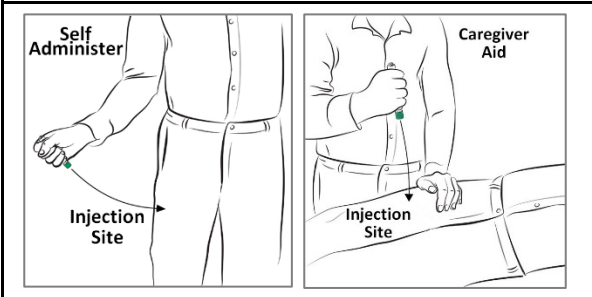
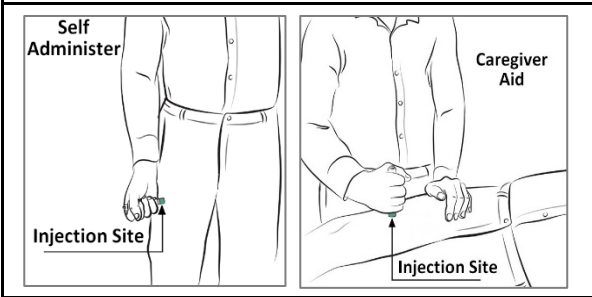
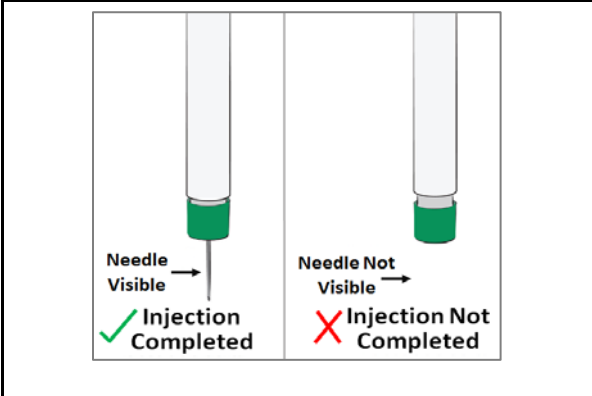


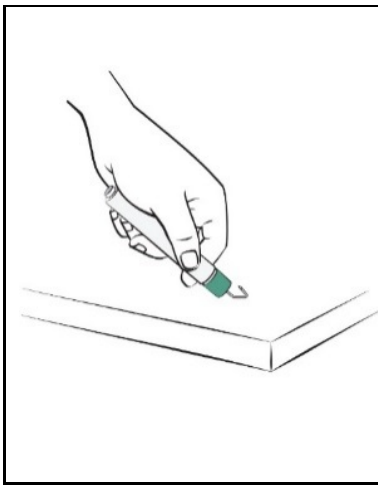
How do I administer the Rafa Atropine Auto-Injector to myself or others?

Caregivers should wear protective garments to avoid exposure to the nerve agent or insecticide (organophosphorus and/or carbamate); protect skin with garments and gloves, and use goggles and masks to protect the face and eyes. If you see someone who has been exposed, avoid contact with that person, including not touching their exposed clothing unless you are properly protected.

Follow the instructions below in **Figure 2** to administer the Rafa Atropine Auto-Injector to yourself or others as soon as possible when symptoms of nerve agent or certain insecticide poisoning appear. Move yourself and the exposed person away from the contaminated area as quickly as possible. Get medical care right away after exposure.

Figure 2. Instructions on how to administer Rafa Atropine Auto-Injector to yourself or others

	<p>A.) Confirm you have the correct dose based on weight or age (see Table 1). Hold the plastic sleeve on both sides of the perforation and tear apart at edge to open. Remove the auto-injector from the plastic sleeve. Be careful not to place fingers on the green tip.</p>
	<p>B.) Firmly hold the auto-injector with the green tip pointed down.</p>
	<p>C.) Pull off the yellow safety cap with your other hand.</p>
	<p>D.) Aim and firmly jab the green tip straight down (a 90° angle) against the outer thigh. The auto-injector device will give the medicine when you do this. You can inject through clothing, but make sure pockets at the injection site are empty.</p> <p>*Infants, small children, and adults who may not have a lot of fat at the injection site should also be injected in the thigh, but before giving the injection, bunch up the thigh to provide a thicker area of injection.</p>
	<p>E.) Hold the auto-injector firmly in place for at least 10 seconds to allow the injection to finish.</p>
	<p>F.) After 10 seconds, remove the auto-injector from the thigh (or from the thigh of the individual to whom you are administering the auto-injector) and massage the injection site in a circle motion for several seconds.</p> <p>Note: If you do not see the needle visible after removal from the thigh it means an injection did not occur. Check to be sure the yellow safety cap has been removed. After yellow safety cap removal has been verified, repeat steps D and E pressing harder against the thigh to activate the injector. If you still do not see the needle, use a new auto-injector and start over again at step A.</p>



G.) After the injection, avoid contact with blood or needle by carefully bending the needle back against the injector using a hard surface. Using the bent needle as a hook, pin the used auto-injectors to the patient's clothing. Alternatively, either place the used auto-injector(s) back into plastic sleeve(s) and leave it next to the patient or write the dose and number of auto-injector(s) used on a triage tag, hand, forehead, chest, etc. Move yourself and the exposed person away from the contaminated area right away. Try to find medical help.

Auto-injectors contain only a single dose. If you need more than 1 injection, obtain a fresh auto-injector, go back to step A, and follow the same instructions for each new auto-injector used.

How should I store the Rafa Atropine Auto-Injector?

Store the Rafa Atropine Auto-Injector between 59°F and 86°F. Do not freeze.

What information should I know about expiration dates for stockpiled Rafa Atropine Auto-Injectors?

FDA may extend the expiration date of the Rafa Atropine Auto-Injector based on FDA's examination of the medication. Any expiration date(s) that FDA may extend in the future will be made available at <https://www.cdc.gov/phpr/stockpile/chempack.htm>.

How do I report side effects I experienced with the Rafa Atropine Auto-Injector?

- Tell your healthcare provider if you experience side effects that bother you or that do not go away.
- Report side effects or medication errors to FDA electronically through MedWatch. Indicate in the MedWatch form that the Rafa Atropine Auto-Injector was used under an EUA and, if possible, which dose was used (i.e., 0.5 mg, 1 mg, or 2 mg) and the number of auto-injectors used.
 - www.fda.gov/medwatch
 - MedWatch Form 3500:
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>
 - 1-800-FDA-1088

For more information:

- Contact your local/state health department and/or EMS or hospital, or talk to your healthcare provider if possible
- Contact the poison control center at 1-800-222-1222 or visit www.aapcc.org
- Visit <https://chemm.nlm.nih.gov>
- Visit <https://www.cdc.gov> or call 1-800-CDC INFO (1-800-232-4630)
- Visit <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm>