


**Emergency Preparedness**
[Bioterrorism and Drug Preparedness](#)
[Anthrax](#)
[Plague](#)
[Radiation Emergencies](#)
[Chemical Agents](#)
[Regulatory Information for Counter-Terrorism Drug Development](#)
[Vaccine Information](#)
[Pediatric Counter-Terrorism Measures](#)
**Questions and Answers on Pyridostigmine Bromide**

1. What is the Food and Drug Administration (FDA) announcing?
2. What is the basis for the approval of pyridostigmine bromide?
3. Why does FDA think pyridostigmine bromide will work in humans if it was only tested in animals?
4. What is Soman?
5. Has pyridostigmine bromide ever been approved for another use?
6. How does pyridostigmine bromide work against Soman?
7. Can be given after exposure to Soman?
8. What are possible side effects of pyridostigmine bromide?
9. Are there any long-term side effects of pyridostigmine bromide?
10. Who should not take pyridostigmine bromide?
11. Was pyridostigmine bromide used in the Gulf War?
12. How is pyridostigmine bromide taken?
13. Can people who are not in the military get pyridostigmine bromide for themselves and their families?

**1. What is the Food and Drug Administration (FDA) announcing?**

FDA is announcing the approval of pyridostigmine bromide to increase survival after exposure to the nerve agent Soman. Pyridostigmine bromide is approved only for combat use by U.S. military personnel.

**2. What is the basis for the approval of pyridostigmine bromide?**

Pyridostigmine bromide was approved under a [FDA rule](#) that allows the agency to rely on animal study data as evidence of effectiveness when studies in humans are not possible. Normally, FDA regulations require studies to be performed in humans but, because exposing humans to nerve agents is too dangerous, effectiveness studies in animals are considered acceptable in such circumstances. The safety data on the use of this product was obtained from humans who took pyridostigmine bromide.

**3. Why does FDA think pyridostigmine bromide will work in humans if it was only tested in animals?**

FDA believes, based on what it knows about the animals studied, that it is reasonably likely that humans will respond similarly. Primarily in studies with monkeys and guinea pigs, pyridostigmine bromide was shown to be effective in protecting against Soman's deadly effects.

**4. What is Soman?**

Soman is a nerve agent that blocks an enzyme muscles need to work properly. Soman exposure can cause loss of muscle control and death if the muscles required for breathing are paralyzed.

[Back to top](#)

**5. Has pyridostigmine bromide ever been approved for another use?**

Yes, pyridostigmine bromide was first approved in 1955 to treat myasthenia gravis, a chronic muscle disease.

**6. How does pyridostigmine bromide work against Soman?**

Pyridostigmine bromide appears to work by preventing Soman from blocking an enzyme that muscles need to work properly. Pyridostigmine bromide must be taken before exposure to Soman. Pyridostigmine bromide alone will not protect against Soman poisoning. However, nerve agent antidotes (atropine and pralidoxime) work better against Soman if pyridostigmine bromide is taken before exposure to Soman.

**7. Can pyridostigmine bromide be given after exposure to Soman?**

No. Military personnel will be told that pyridostigmine bromide is not expected to be effective if taken after exposure to Soman. Military personnel will also be advised that taking pyridostigmine bromide after exposure to Soman can make the harmful effects of Soman exposure worse.

**8. What are possible side effects of pyridostigmine bromide?**

Some side effects that may occur include:

- stomach cramps
- gas
- diarrhea
- nausea
- increased urge to urinate
- drooling
- sweating
- headaches
- dizziness
- eye tearing
- blurred vision
- runny nose

- shortness of breath
- acid stomach, including heartburn or reflux
- tingling of fingers, toes, arms, and legs
- muscle twitching, weakness, or cramping

[Back to top](#)

**9. Are there any long-term side effects of pyridostigmine bromide?**

Pyridostigmine bromide was first approved in 1955, and has been prescribed by doctors to treat patients with myasthenia gravis for over 40 years. To date, no long-term health problems thought to be associated with pyridostigmine bromide have been reported by these patients.

**10. Who should not take pyridostigmine bromide?**

Pyridostigmine bromide should not be taken by military personnel who:

- have a history of bowel or bladder blockage
- have sensitivity to certain medicines used during surgery (like physostigmine, edrophonium, neostigmine, and ambenonium).

Military personnel should tell their doctor or medic before taking pyridostigmine bromide if they:

- take medications for glaucoma or blood pressure
- have asthma
- are pregnant
- are allergic to bromide.

**11. Was pyridostigmine bromide used in the Gulf War?**

Yes. At the time of the Gulf War, pyridostigmine bromide was not approved to prevent death from exposure to a nerve agent. However, during that time, FDA allowed the military to distribute pyridostigmine bromide as an investigational new drug for that use. Today's action provides FDA approval for military combat use of pyridostigmine bromide to prevent death from exposure to Soman.

[Back to top](#)

**12. How is pyridostigmine bromide taken?**

The approved dose of pyridostigmine bromide is one 30-mg. tablet every 8 hours to be started at least several hours prior to Soman exposure. Pyridostigmine bromide is taken within 8 hours before, but not right before, exposure to nerve agent. (If pyridostigmine bromide is taken right before (when the nerve gas attack alarm is given) or during nerve agent exposure, it may not work and may make the effects of Soman worse.) The patient information sheet that accompanies the medication emphasizes that at the first sign of nerve agent poisoning military personnel should not take any more pyridostigmine bromide and should immediately take the nerve agent antidotes (atropine and pralidoxime).

**13. Can people who are not in the military get pyridostigmine bromide for themselves and their families?**

No. Pyridostigmine bromide is only approved for use in military combat situations, therefore pyridostigmine bromide is only available to military personnel.

Page Last Updated: 04/30/2009

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).



[Accessibility](#) | [Contact FDA](#) | [Careers](#) | [FDA Basics](#) | [FOIA](#) | [No Fear Act](#) | [Site Map](#) | [Transparency](#) | [Website Policies](#)

**U.S. Food and Drug Administration**

10903 New Hampshire Avenue  
 Silver Spring, MD 20993  
 Ph. 1-888-INFO-FDA (1-888-463-6332)  
[Email FDA](#)



[For Government](#) | [For Press](#)

- [Combination Products](#)
- [Advisory Committees](#)
- [Science & Research](#)
- [Regulatory Information](#)
- [Safety](#)
- [Emergency Preparedness](#)
- [International Programs](#)
- [News & Events](#)
- [Training and Continuing Education](#)
- [Inspections/Compliance](#)
- [State & Local Officials](#)
- [Consumers](#)
- [Industry](#)
- [Health Professionals](#)

