



Drug Information

[CDER Home](#) | [Site Info](#) | [Contact Us](#) | [What's New](#)

Search

[About CDER](#)[Drug Information](#)[Regulatory Guidance](#)[CDER Calendar](#)[Specific Audiences](#)[CDER Archives](#)

Questions and Answers on Prussian Blue

1. [What has the Food and Drug Administration \(FDA\) determined about Prussian blue?](#)
2. [Are there any approved Prussian blue drug products available in the U.S.?](#)
3. [What is Prussian blue?](#)
4. [Since Prussian blue has been around for so many years why did FDA make this determination?](#)
5. [Why is FDA saying Prussian blue can be indicated just for treatment of patients contaminated with radioactive cesium and radioactive or non-radioactive thallium only?](#)
6. [What is cesium?](#)
7. [What is thallium?](#)
8. [What is a "dirty bomb"?](#)
9. [How can radioactive materials be used in the medical field and also be components of a dirty bomb?](#)
10. [How does Prussian blue work?](#)
11. [Are there any side effects associated with taking Prussian blue?](#)
12. [How soon after exposure to radioactive cesium or to thallium does somebody have to receive Prussian blue to avoid illness and death?](#)
13. [Can more than one company gain approval for Prussian blue?](#)
14. [When will Radiogardase be available?](#)
15. [Can my doctor write a prescription for Prussian blue for me to keep on hand?](#)
16. [How do I know that Prussian blue will be available in case of an emergency?](#)
17. [Will Prussian blue be added to the National Stockpile?](#)

1. What has the Food and Drug Administration (FDA) determined about Prussian blue?

The FDA has determined that the 500 mg Prussian blue capsules, when manufactured under the conditions of an approved New Drug Application (NDA), can be found safe and effective for the treatment of known or suspected internal contamination with radioactive cesium, radioactive thallium, or non-radioactive thallium. This decision is based on a careful review of published literature articles containing reports, data, and experiences of people who were exposed to high levels of thallium or cesium-137 and were treated effectively with Prussian blue.

2. Are there any approved Prussian blue drug products available in the U.S.?

Yes. The first approval of Prussian blue, known as Radiogardase, was October 2, 2003.

Radiogardase is manufactured by HEYL Chemisch-pharmazeutische Fabrik GmbH & Co. KG.

3. **What is Prussian blue?**

Prussian blue has been used as a pigment in industry and for artists since 1704. Prussian blue has been used as a treatment to speed up the excretion of radioactive cesium or non-radioactive thallium, from the body according to studies reported in the literature.

4. **Since Prussian blue has been around for so many years why did FDA make this determination?**

FDA wants doctors to know that Prussian blue can be used to treat contamination that may occur as a result of a routine accidental poisoning, as well as contamination associated with a terrorist event. In an effort to ensure that Prussian blue consistently meets high standards of quality, and that proper instructions for use are available with the product, FDA continues to encourage industry to file marketing applications.

The FDA has encouraged manufacturers to submit applications for Prussian blue as part of our efforts to encourage the development of drug products for treatment of people exposed to harmful levels of radioactive materials and poisons and for counter-terrorism agents.

[Back to Top](#)

5. **Why is FDA saying Prussian blue can be indicated just for treatment of patients contaminated with radioactive cesium and radioactive or non-radioactive thallium only?**

We are unaware of any clinical data demonstrating the effectiveness of Prussian blue for treating patients contaminated with any other elements.

When the nature of the radioactive contamination is not known, Prussian blue may be given together with other drugs, such as potassium iodide, calcium or zinc DTPA, or sodium alginate, with known effectiveness in treating contamination from other radioactive substances.

6. **What is cesium?**

Cesium is a natural metal element. Cesium-137, a radioactive form of cesium, was discovered in 1941. Cesium-137 is still widely used today by industry and the medical community. It is used in a variety of devices, and is used as a source of radiation to treat certain cancers. Cesium-137 has the potential to be included as a part of a "dirty bomb."

7. **What is thallium?**

Thallium is a natural element found in many minerals. Thallium is very toxic and different thallium compounds have a variety of uses—from rat and ant poison to the manufacture of optical glass and other industrial uses. The radioactive form of thallium (thallium-201) is approved as a radio-imaging drug used in small doses for medical procedures. This use of thallium in low doses is very safe.

Exposure to a high dose of thallium generally results in severe stomach symptoms, followed by brain symptoms, and sometimes death. However, the radioactive form of thallium (thallium-201) that is used for medical purposes is used in such small amounts that exposure to high

doses is unlikely.

8. What is a "dirty bomb"?

A "dirty bomb" is a conventional, not a nuclear, bomb. It does not have the destructive power of a nuclear bomb and does not involve a nuclear explosion. Dirty bombs could contain radiological materials such as radioactive cesium (cesium-137) or other radioactive elements. Such a bomb could spread radiation over a wide area causing illness and even death.

[Back to Top](#)

9. How can radioactive materials be used in the medical field and also be components of a dirty bomb?

Cesium-137 and thallium-201 exposure can be beneficial to certain patients in controlled settings involving limited exposure. In the medical field, cesium-137 is used as a source of radiation for treatment of various forms of cancer. Thallium-201 is used in very small doses as a radioimaging drug. However, a dirty bomb could contain large amounts of cesium-137 or other radioactive elements.

10. How does Prussian blue work?

Prussian blue works using a mechanism known as ion exchange. Cesium or thallium that have been absorbed into the body are removed by the liver and passed into the intestine and are then re-absorbed into the body (entero-hepatic circulation). Prussian blue works by trapping thallium and cesium in the intestine, so that they can be passed out of the body in the stool rather than be re-absorbed. If persons are exposed to radioactive cesium, radioactive thallium, or non-radioactive thallium, taking Prussian blue may reduce the risk of death and major illness from radiation or poisoning.

11. Are there any side effects associated with taking Prussian blue?

The most commonly reported side effects are constipation and upset stomach.

12. How soon after exposure to radioactive cesium or to thallium does somebody have to receive Prussian blue to avoid illness and death?

Prussian blue should be taken as soon as possible after exposure. However, even when treatment cannot be started right away, patients should be given Prussian blue as soon as it becomes available because it is still effective even after time has elapsed since exposure.

13. Can more than one company gain approval for Prussian blue?

Yes. However, in addition to the protection provided by patents issued by the U.S. Patent and Trademark Office, Prussian blue drug products approved by FDA may be protected from competition by periods of marketing exclusivity. Please refer to the guidance document issued in January 2003, on submitting a new drug application for details.

[Back to Top](#)

14. When will Radiogardase be available?

The sponsor anticipates that it will have product available for shipment approximately six to eight weeks after approval.

15. Can my doctor write a prescription for Prussian blue for me to keep on hand?

Prussian blue is available only by prescription and should be given only under the supervision of a physician after assessing your medical condition. It is only effective to treat contamination with radioactive cesium or thallium. The dose and duration of treatment depends on the amount of contamination a person is exposed to. Therefore, this drug should be given only when the physician has determined your need for it.

16. How do I know that Prussian blue will be available in case of an emergency?

The U.S. government makes sure that needed medications, especially medicines that may be needed to treat a terrorist threat, are stored in sufficient quantity to provide treatment if there is an emergency.

17. Will Prussian blue be added to the National Stockpile?

It is already part of the National Stockpile of drugs that can be used in an emergency situation.



[Back to Top](#)



[Back to Prussian Blue](#)

FDA/Center for Drug Evaluation and Research
Last Updated: June 30, 2004
Originator: OTCOM/DLIS
HTML by SJW