

Radiation/Nuclear Emergency: How to Use Radiogardase® (Prussian Blue Insoluble) Emergency Use Authorization Fact Sheet for Parents/Guardians

Tests show that your child has a radioactive material called cesium (see-zee-um) inside his/her body. Doctors have a prescription medicine called Radiogardase® (ray-dee-oh-gar-dase) which is also called Prussian Blue Insoluble (PBI) that can be used to help remove radioactive cesium out of the body. The Food and Drug Administration (FDA) has issued this Emergency Use Authorization (EUA) to allow the use of PBI in children who are between 6 and 23 months old during this emergency.

What is cesium?

Cesium is a natural metal element. Its radioactive form, called Cesium-137, is commonly used in industry as a sterilization tool and medicine as a source of radiation to treat certain cancers. However, its use is in controlled settings to make sure exposure to cesium-137 is short and limited.

Why is radioactive cesium harmful?

During a radiation/nuclear emergency, radioactive materials are released in the air and can fall onto surfaces. When radioactive cesium gets into the body either through breathing it in or eating/drinking contaminated food/water, it can harm the body by exposing it to unwanted radiation for a long period of time. Having a large amount of radiation inside the body can cause illnesses such as acute radiation syndrome and cancer(s) to develop, all which can lead to early death.

Children are especially vulnerable to the harmful effects of radiation since they have more cells that are rapidly dividing and generally have longer lifespans ahead of them to allow cancer(s) to develop. They also can receive more unwanted radiation since they breathe in more air for their size than adults and often spend more time outside and on the ground.

What is Prussian blue insoluble (PBI)?

PBI has been FDA-approved for many years as a safe and effective medicine to help remove radioactive cesium from the body in children (2 years old and older) and adults, including pregnant women.

It works by trapping radioactive cesium in the intestines to keep it from being re-absorbed into the body. The trapped radioactive cesium is then moved through the intestines and excreted out of the body mainly as stool and some in the urine. Thus, PBI can reduce the amount of time your child's body is exposed to unwanted radiation from about 110 days to 30 days when properly taken every day.

However, PBI cannot reverse damage already done to the body from radioactive cesium before PBI treatment and it cannot remove other radioactive material that may be in your child's body.

Where do I get PBI?

Prussian blue insoluble is a prescription medication that will be given either through your child's doctor, public health authority, or other medical staff after your child has been evaluated. In order to receive this medication, your child *must* be 1) between the ages of 6 months old to 23 months, 2) weighs 13 pounds or more, and 3) able to safely eat food such as semi-solid foods like baby food, applesauce, or pudding because the medicine needs to be mixed with food.

Your child may have to stay in the hospital while they are getting the medicine or you will be given the medication and the specific dose (based on body weight) to give to your child at home, along with appointment(s) to follow-up with medical staff to make sure your child is responding well to the medication.

How does my child take PBI?

Prussian blue insoluble is usually taken by mouth as a gelatin capsule 3 times a day for about 30 days. However children in this age group are generally unable to swallow PBI capsules, so this medication should be given to

your child as a drug-food mixture. (See **Instructions on [How to Open Capsules and Make Drug-Food Mixture along with dosing based on body weight](#)**).

- Do not grind up or break the blue granules into a fine powder. Gently mix the medication into the appropriate semi-solid food of your choice.
- Do not skip doses. However, if your child misses a dose, **do NOT take 2 doses at the same time**. Take the next dose as scheduled.
- Keep the capsules dry. Store PBI capsules with its original container at room temperature (59–86°F).
- Keep PBI safely away from children and pets. Call the poison control center if children or pets swallow PBI by accident (1-800-222-1222).

If you are giving this medication to your child at home, then make sure you receive contact information for who to call if you have other questions/concerns, a follow-up appointment, and the detailed at-home instructions on [How to Open Capsules and Make Drug-Food Mixture](#). You should also receive other instructions on how to safely handle and dispose of your child's stool, urine, soiled clothing/diapers.

What are the common side effects from PBI?

Upset stomach and constipation (hard stools) were the most common side effects reported in patients who have received PBI. Your child's doctor may give your child a stool softener or laxative to help keep your child from having hard stools. Your child's stool will turn blue while they are taking PBI. It may also stain your child's mouth and teeth blue but it is unknown if the blue color will go away in younger children.

What are possible serious side effects of PBI?

PBI is made from a mixture of iron and cyanide salts. Although unlikely, it is possible that very small amounts of cyanide may be released when it is being mixed. The amount of cyanide released however, would be far below levels considered unsafe and is not expected to be a medical concern. There also have been no reports of cyanide poisoning in patients that have received PBI. It is also possible that PBI can cause electrolyte disturbances, especially if your child has any pre-existing heart problems or other medical conditions resulting in electrolyte imbalances, severe constipation, and/or intestinal obstruction. Your child's doctor or medical staff will be monitoring your child for these possible serious side effects.

If any of these serious side effects continue or worsen, let your child's doctor know or get medical help right away by calling 911. For a complete list of side effects, please see Radiogardase's package insert (<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=baa68c79-5f3d-468a-a510-58b9e978cd50&audience=consumer>)

What does your child's doctor need to know before giving my child PBI?

If your child has gastrointestinal mobility disorder, chronic constipation, electrolyte abnormalities, or other medical condition(s) and/or taking other medication(s), then you should talk with your child's doctor or medical staff before giving your child this medicine.

What else do I need to know about PBI?

Some people have to take Prussian blue for at least 30 days. The same could be true for your child. It all depends on how fast Prussian blue works. This is different for each person. Your child will need a follow-up appointment so the medical staff can do some tests to check how well PBI is working and monitor your child for any possible side effects.

No studies have been done in young children (less than 2 years old), so its effects are not fully known. However, during this emergency, FDA is allowing emergency use of PBI to treat children between 6 and 23 months old that have radioactive cesium in their body since PBI will likely work in the same way.

What if I stop or decide not to give my child PBI?

It is your choice to treat or not to treat your child with PBI. At any time, you may tell your child's doctor to start or stop giving PBI. Whatever you decide, it will not change your child's regular medical care. However if you chose to stop or not give your child PBI, the harmful effects of radiation cesium inside your child's body will remain.

What are the other choices for treatment?

Prussian blue is the only medicine that can use to treat radioactive cesium contamination and there are no other FDA-approved medications to remove radioactive cesium out of your child's body. This is true for both children and adults.

Prussian blue artist's dye or any industrial use of prussian blue as a pigment cannot be used to treat radioactive cesium in your child's body and may be harmful to your child's health.

Risk-Benefit Statement

The expected benefit of PBI to quickly remove radioactive cesium out of your child's body to reduce the risks of harmful radiation effects, cancer, and early death outweigh the risks of possible serious side effects of PBI.

How do I report side effects or medication errors?

Tell your child's healthcare provider right away if your child gets side effects that are bothersome or that do not go away. Report side effects or medication errors to FDA MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

A federal program called Countermeasures Injury Compensation Program may help pay for costs of medical care and other specific expenses of some people who have been seriously injured by certain medicines or vaccines. To learn more about this program: visit www.hrsa.gov/cicp or call 1-855-266-2427 (toll-free).

How can I learn more?

Contact your state/local public health department or your child's healthcare provider. You can also visit <http://emergency.cdc.gov/radiation/> or www.fda.gov

Giving Prussian Blue Insoluble (PBI) to Children Aged 6 to 23 Months At-Home Instructions on How to Open Capsules and Make Drug-Food Mixture

Before you give your child PBI at-home, make sure your child meets these 3 criteria:

- 1) is between the ages of 6 to 23 months old;
- 2) weighs 6 kilograms (13 pounds) or more; and
- 3) is currently able to eat semi-solid foods. If your child cannot meet these criteria then contact your healthcare provider for further instructions.

Each capsule of PBI contains 500 milligrams (mg) of drug. **This drug-food mixture needs to be given by mouth three times a day (morning, afternoon, and evening) for 30 days in a row** or as determined by your child's doctor. Your child's dose is based on their weight. The table on the next page provides more details on the timing and amount of dose and food to mix.

What you will need:

- 1–2 Prussian blue insoluble capsule(s) depending on weight (1 capsule = 500 mg of drug)
- 1 Tablespoon
- 1 Small bowl
- Your choice of semi-solid foods (age-appropriate foods should be chosen that your child enjoys eating already) such as baby food (can include infant cereal, pre-mixed with breast milk or formula), apple sauce, yogurt, pudding, or chocolate syrup



Step-by-step Instructions for Making the Drug-Food Mixture:

Step 1: Find your child's weight in the table on the next page. Find the number of capsules and number of tablespoons of semi-solid food needed for Steps 2 and 3.

Step 2: Carefully pull each Prussian blue insoluble capsule open and pour out the contents (blue granules) completely into a small bowl. Make sure no granules are left inside the capsule. Discard the empty capsule.

























Step 3:

- Put a small amount (1 or 2 tablespoons) of semi-solid food into the bowl containing the Prussian blue insoluble granules.
- Mix the granules into the food gently with a spoon. **IMPORTANT: DO NOT MIX VIGOROUSLY. DO NOT GRIND OR BREAK THE GRANULES INTO FINE POWDER.** The drug-food mixture should have a sandy texture and will be blue in color.
- Give the entire amount of the drug-food mixture within 30 minutes of preparation.
- Repeat the above steps with each dose. Use a clean tablespoon and bowl each time.

Amount of Drug-Food Mixture to Give Each Day

Directions: Find the number of PBI capsule(s) needed based on child's weight. Open capsule(s) as directed.

Empty contents of the capsule(s) into a bowl containing semi-solid food. Gently mix together to make a drug-food mixture for your child.

Weight in pounds (Weight in kg)	Time of Day	Dose (Number of Prussian blue insoluble Capsules Needed)	Number of Tablespoon(s) of Semi-solid Food Needed
13–27 pounds (6–12 kg)	Morning	1 capsule (500 mg) 	 1 tablespoon (15 mL) of semi-solid food
	Afternoon	1 capsule (500 mg) 	 1 tablespoon (15 mL) of semi-solid food
	Evening	1 capsule (500 mg) 	 1 tablespoon (15 mL) of semi-solid food
28–35 pounds (13–16 kg)	Morning	2 capsules (1,000 mg) 	 2 tablespoons (30 mL) of semi-solid food
	Afternoon	1 capsule (500 mg) 	 1 tablespoon (15 mL) of semi-solid food
	Evening	1 capsule (500 mg) 	 1 tablespoon (15 mL) of semi-solid food
36–43 pounds (17–19 kg)	Morning	2 capsules (1,000 mg) 	 2 tablespoons (30 mL) of semi-solid food
	Afternoon	2 capsules (1,000 mg) 	 2 tablespoons (30 mL) of semi-solid food
	Evening	1 capsule (500 mg) 	 1 tablespoons (15 mL) of semi-solid food
>44 pounds (>20 kg)	Morning	2 capsules (1,000 mg) 	 2 tablespoons (30 mL) of semi-solid food
	Afternoon	2 capsules (1,000 mg) 	 2 tablespoons (30 mL) of semi-solid food
	Evening	2 capsules (1,000 mg) 	 2 tablespoons (30 mL) of semi-solid food