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# INSOLUBLE PRUSSIAN BLUE

## MICROMEDEX® POISINDEX® MANAGEMENT

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## POISINDEX® Managements

# INSOLUBLE PRUSSIAN BLUE

### 0.0 OVERVIEW

LIFE SUPPORT

CLINICAL EFFECTS

LABORATORY/MONITORING

TREATMENT OVERVIEW

RANGE OF TOXICITY

### 0.1 LIFE SUPPORT

**A)** This overview assumes that basic life support measures have been instituted.

### 0.2 CLINICAL EFFECTS

**0.2.1** SUMMARY OF EXPOSURE

**A)** WITH THERAPEUTIC USE

**1)** Constipation, gastric distress, and asymptomatic hypokalemia have been reported in patients taking insoluble **Prussian** blue.

**B)** WITH POISONING/EXPOSURE

**1)** Obstipation, obstruction, or severe hypokalemia may occur following overdose.

**0.2.20** REPRODUCTIVE

**A)** US Food and Drug Administration pregnancy category C

### 0.3 LABORATORY/MONITORING

**A)** Following an ingestion, Insoluble **Prussian** blue is negligibly absorbed through the intact gastrointestinal tract. Therapeutic or toxic blood concentrations have not been established.

**B)** Obstipation, obstruction, hypokalemia or other electrolyte disturbance may occur following overdose. Monitor for any fluid and electrolyte abnormalities.

**C)** Systemic toxicity requiring monitoring of liver, kidney or hematologic function has not been reported.

**D)** Insoluble **Prussian** blue may bind some orally administered therapeutic dugs. As appropriate, blood concentrations or clinical response to oral medications should be monitored (Prod Info Radiogardase(TM), 2003).

### 0.4 TREATMENT OVERVIEW

**0.4.2** ORAL/PARENTERAL EXPOSURE

**A)** Overdose information is limited. Following an oral ingestion, Insoluble **Prussian** blue is negligibly absorbed through the intact gastrointestinal tract. Gastrointestinal decontamination is generally not necessary. Treatment is symptomatic and supportive.

### 0.5 RANGE OF TOXICITY

**A)** A minimum toxic dose has not been established. Doses up to 10 g/day have been well tolerated.

### 1.0 SUBSTANCES INCLUDED/SYNONYMS

THERAPEUTIC/TOXIC CLASS

SPECIFIC SUBSTANCES

AVAILABLE FORMS/SOURCES

**1.1 THERAPEUTIC/TOXIC CLASS**

**A)** Insoluble **Prussian** blue, also known as ferric ferrocyanide, is a negligibly absorbable binding agent used for the treatment of radioactive cesium, radioactive thallium, and thallium contamination.

**1.2 SPECIFIC SUBSTANCES**

**1)** Berlin blue
**2)** Chinese blue
**3)** CI Pigment blue 27
**4)** Color Index No 77510
**5)** Ferric hexacyanoferrate(II)
**6)** Ferric(III) hexacyanoferrate(II)
**7)** Ferrate(4-), hexacyano-, iron(3+)
**8)** Ferrate(4-), hexakis(cyano-C)-, iron
**9)** Ferric ferrocyanoferrate
**10)** Ferrihexacyanoferrate
**11)** Ferric ferrocyanide
**12)** Ferrocin
**13)** Ferrotsin
**14)** Hamburg blue
**15)** Iron blue
**16)** Iron cyanide
**17)** Iron(3+) ferrocyanide
**18)** Iron(III) ferrocyanide
**19)** Milori blue
**20)** Mineral blue
**21)** Paris blue
**22)** Potassium ferric hexacyanoferrate
**23)** **Prussian** blue
**24)** Tetrairon tris (hexacyanoferrate)
**25)** Molecular Formula: C18-Fe3-N18.4Fe (ferric hexacyanoferrate)
**26)** CAS 14038-43-8 (ferric hexacyanoferrate)
**27)** CAS 12230-15-2 (potassium ferric hexacyanoferrate)
**28)** FERRIC HEXACYANOFERRATE
**29)** FERRICYANIDE
**30)** FERROCYANIDE
**31)** **PRUSSIAN** BLUE, INSOLUBLE

**1.2.1** MOLECULAR FORMULA

**1)** C18-Fe3-N18.4Fe

**1.6 AVAILABLE FORMS/SOURCES**

**A)** FORMS

**1)** Insoluble **Prussian** blue is available as 0.5 gram blue powder in gelatin capsules for oral administration by prescription. Thirty capsules are packaged in a brown glass bottle (Prod Info Radiogardase(TM), 2003a). Non pharmaceutical-grade **Prussian** blue (e.g. artists' dye) is not intended for human consumption and should not be used for treatment (Centers for Disease Control, 2004) .

**B)** SOURCES

**1)** The Heyltex Corporation, Katy, Texas, a subsidiary of Heyl Chemisch-pharmazeutische Fabrik, is the only U.S.distributor for **Prussian** blue (Radiogardase®) – (281) 395-7040; URL: http://www.heyltex.com/; email: heyltex@houston.rr.com.

**2)** The CDC has included **Prussian** blue in the U.S. Strategic National Stockpile (SNS) of pharmaceuticals and medical supplies. CDC Emergency Response Hotline: 770-488-7100 (for use by state and local health

officials and healthcare providers).

**3)** Radiation Emergency Assistance Center/Training Site (REAC/TS), Oak Ridge Institute for Science and Education (ORISE) may serve as a further source of assistance in obtaining **Prussian** blue: (865) 576-3131; emergency number: (865) 576-1005; URL: http://orise.orau.gov/reacts/; email: reacts@orau.gov.

**C)** USES

**1)** Insoluble **Prussian** blue is used to treat patients with known or suspected internal contamination with radioactive cesium, radioactive thallium, or non-radioactive thallium, to increase their rates of elimination (Prod Info Radiogardase(TM), 2003a). There is one case report of use in non-radioactive cesium toxicity (Thurgur et al, 2006).

## 3.0 CLINICAL EFFECTS

SUMMARY OF EXPOSURE

GASTROINTESTINAL

FLUID-ELECTROLYTE

REPRODUCTIVE

CARCINOGENICITY

OTHER

### 3.1 SUMMARY OF EXPOSURE

**A)** WITH THERAPEUTIC USE

**1)** Constipation, gastric distress, and asymptomatic hypokalemia have been reported in patients taking insoluble **Prussian** blue.

**B)** WITH POISONING/EXPOSURE

**1)** Obstipation, obstruction, or severe hypokalemia may occur following overdose.

### 3.8 GASTROINTESTINAL

**3.8.2** CLINICAL EFFECTS

**A)** CONSTIPATION

**1)** WITH THERAPEUTIC USE

**a)** Insoluble **Prussian** blue may cause constipation or obstipation. This reduction in GI motility will slow the transit time of radionuclides bound to the drug in the GI tract, and may increase the absorbed radiation dose to the GI mucosa (Hoffman, 2003; Prod Info Radiogardase(TM), 2003a; Thompson & Church, 2001; Pearce, 1994).

**b)** Mild to moderate constipation has been reported in 10 of 42 (24%) patients in the Goiania incident treated with insoluble **Prussian** blue (Prod Info Radiogardase(TM), 2003a).

**c)** Undefined gastric distress has been reported in patients taking 20 grams/day of insoluble **Prussian** blue (Prod Info Radiogardase(TM), 2003a).

**d)** Insoluble **Prussian** blue may impart a blue discoloration to the stools, and to the mouth and teeth if the capsules are opened and mixed with food or fluids (Prod Info Radiogardase(TM), 2003a). Bluish discoloration of sweat and tears may occur with prolonged therapy (Hoffman, 2003).

**2)** WITH POISONING/EXPOSURE

**a)** Obstipation, obstruction, or severe decrease in electrolytes may occur following overdose (Prod Info Radiogardase(TM), 2003a).

### 3.12 FLUID-ELECTROLYTE

**3.12.2** CLINICAL EFFECTS

**A)** HYPOKALEMIA

**1)** WITH THERAPEUTIC USE

**a)** Insoluble **Prussian** blue may bind electrolytes in the gastrointestinal tract. Hypokalemia

(potassium 2.5 to 2.9) was reported in 3 of 42 patients (7%) treated with Insoluble **Prussian** blue (Thompson & Callen, 2004; Prod Info Radiogardase(TM), 2003a; Thompson & Church, 2001).

**B)** ELECTROLYTES ABNORMAL

**1)** WITH POISONING/EXPOSURE

**a)** Severe hypokalemia or other electrolyte disturbances may occur following overdose (Prod Info Radiogardase(TM), 2003a).

## 3.20 REPRODUCTIVE

### 3.20.1 SUMMARY

**A)** US Food and Drug Administration pregnancy category C

### 3.20.3 EFFECTS IN PREGNANCY

**A)** PREGNANCY CATEGORY

**1)** US Food and Drug Administration pregnancy category C (Prod Info Radiogardase(TM), 2003a).

**2)** The effects of Insoluble **Prussian** blue in human offspring are unknown since there are no studies in pregnant women. Insoluble **Prussian** blue is negligibly absorbed from the GI tract, and effects on the fetus are not expected (Prod Info Radiogardase(TM), 2003). Because both cesium and thallium can cross the placenta and induce fetal toxicity, a risk benefit analysis would support the use of Insoluble **Prussian** blue in significant radioactive or non-radioactive cesium or thallium exposure. The decision not to use Insoluble **Prussian** blue in one patient exposed to cesium-137 during her 4th month of pregnancy resulted in a neonatal cesium-137 concentration at birth identical to that of the mother(Prod Info Radiogardase(TM), 2003)

**3)** A female exposed to a thallium rodenticide during her 13th week of pregnancy had a 24 hour urine thallium concentration of 3400 mcg/L (normal <5 mcg/L) 6 weeks after the exposure. Chelation with **Prussian** blue improved her clinical status and she was discharged from the hospital. Approximately 11 to 12 weeks after the thallium exposure she spontaneously aborted a child with normal external morphology for its estimated gestational age (Hoffman, 2000).

### 3.20.4 EFFECTS DURING BREAST-FEEDING

**A)** BREAST MILK

**1)** Breast-feeding studies have not been conducted with Insoluble **Prussian** blue; however, since it is not absorbed from the GI tract, its excretion in milk is highly unlikely (Prod Info Radiogardase(TM), 2003; Prod Info Radiogardase(TM), 2003a).

## 3.21 CARCINOGENICITY

### 3.21.1 IARC CATEGORY

**A)** IARC Carcinogenicity Ratings for CAS14038-43-8 (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2006; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010a; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2008; IARC, 2004):

**1)** Not Listed

## 3.23 OTHER

### 3.23.2 CLINICAL EFFECTS

**A)** TOXIC EFFECT OF CYANIDE

**1)** WITH THERAPEUTIC USE

**a)** The release and absorption of cyanide from Insoluble **Prussian** blue are minimal (<0.1% calculated and observed) and clinically irrelevant in normal situations. There is no past clinical evidence of cyanide toxicity in patients treated in normal situations. Very low-dose cyanide exposure effects over a 6-month course of **Prussian** blue treatment are unknown (Thompson & Callen, 2004).

**2)** WITH POISONING/EXPOSURE

**a)** The release and absorption of cyanide from Insoluble **Prussian** blue are minimal (<0.1% calculated and observed). Cyanide release was calculated between 1.6 and 2.9 mg/24 hours given a dose of 20 grams and a gastrointestinal transit time of 24 hours(Verzijl et al, 1993). In three male volunteers, 2 milligrams of non-complex bound cyanide (0.03 mg cyanide/kg) were absorbed from 500 mg oral potassium ferric hexacyanoferrate(II), about a factor of 20 to 100 below the lethal dose

in humans (Nielsen et al, 1990). Cyanide release is enhanced by low pH, and might be increased in conditions such as Zollinger-Ellison syndrome or gastrinemia, or massive overdose . Very low-dose cyanide exposure effects over a 6-month course of **Prussian** blue treatment are unknown (Thompson & Callen, 2004).

**b)** One study determined that incubation pH and exposure time were two major factors to influence the release of cyanide from **Prussian** blue. The greatest amount of cyanide was released from **Prussian** blue at a pH of 1 (135 mcg/g) and lowest amount at a pH of 5 to 7 (21 mcg/g). It was quantitatively estimated that the maximal amount of cyanide released from 17.5 g of **Prussian** (the highest recommended daily dose) was about 1.6 mg, which is considerably less than the reported minimal lethal dose of cyanide (approximately 50 mg) (Yang et al, 2007).

## 4.0 LABORATORY/MONITORING

### 4.1 MONITORING PARAMETERS/LEVELS

**4.1.1** SUMMARY

**A)** Following an ingestion, Insoluble **Prussian** blue is negligibly absorbed through the intact gastrointestinal tract. Therapeutic or toxic blood concentrations have not been established.

**B)** Obstipation, obstruction, hypokalemia or other electrolyte disturbance may occur following overdose. Monitor for any fluid and electrolyte abnormalities.

**C)** Systemic toxicity requiring monitoring of liver, kidney or hematologic function has not been reported.

**D)** Insoluble **Prussian** blue may bind some orally administered therapeutic dugs. As appropriate, blood concentrations or clinical response to oral medications should be monitored (Prod Info Radiogardase(TM), 2003).

## 6.0 TREATMENT

LIFE SUPPORT

MONITORING

ORAL EXPOSURE

### 6.1 LIFE SUPPORT

**A)** Support respiratory and cardiovascular function.

### 6.4 MONITORING

**A)** Following an ingestion, Insoluble **Prussian** blue is negligibly absorbed through the intact gastrointestinal tract. Therapeutic or toxic blood concentrations have not been established.

**B)** Obstipation, obstruction, hypokalemia or other electrolyte disturbance may occur following overdose. Monitor for any fluid and electrolyte abnormalities.

**C)** Systemic toxicity requiring monitoring of liver, kidney or hematologic function has not been reported.

**D)** Insoluble **Prussian** blue may bind some orally administered therapeutic dugs. As appropriate, blood concentrations or clinical response to oral medications should be monitored (Prod Info Radiogardase(TM), 2003).

### 6.5 ORAL EXPOSURE

**6.5.1** PREVENTION OF ABSORPTION/PREHOSPITAL

**A)** Significant toxicity is unlikely. Following an oral ingestion, Insoluble **Prussian** blue is negligibly absorbed through the intact gastrointestinal tract. Gastrointestinal decontamination is generally not needed. Treatment is symptomatic and supportive.

**6.5.2** PREVENTION OF ABSORPTION

**A)** Significant toxicity is unlikely. Following an oral ingestion, Insoluble **Prussian** blue is negligiblyabsorbed through the intact gastrointestinal tract. Gastrointestinal decontamination is generally not needed. Treatment

is symptomatic and supportive.

**6.5.3** TREATMENT

**A)** SUPPORT

**1)** Treatment is symptomatic and supportive. Obstipation, obstruction, hypokalemia or other electrolyte disturbances may occur following overdose. Correct any fluid and electrolyte abnormalities. Monitor patient for abdominal pain, obstipation or bowel obstruction. Consider use of a laxative or cathartic to prevent constipation.

**B)** MONITORING OF PATIENT

**1)** Obstipation, obstruction, or electrolytes abnormalities may occur following overdose. Monitor for any fluid and electrolyte abnormalities.

**2)** Systemic toxicity requiring monitoring of other liver, kidney or hematologic factors has not been reported.

## 7.0 RANGE OF TOXICITY

SUMMARY

THERAPEUTIC DOSE

MAXIMUM TOLERATED EXPOSURE

WORKPLACE STANDARDS

TOXICITY INFORMATION

### 7.1 SUMMARY

**A)** A minimum toxic dose has not been established. Doses up to 10 g/day have been well tolerated.

### 7.2 THERAPEUTIC DOSE

**7.2.1** ADULT

**A)** RADIOACTIVE CESIUM OR THALLIUM

**1)** ADULTS AND ADOLESCENTS 13 YEARS OF AGE OR OLDER - 3 grams orally three times a day; treatment should be initiated as soon as possible after contamination is suspected, and should be continued for a minimum of 30 days, and continued thereafter based on the level of contamination and the judgment of the clinician. When internal radioactivity has decreased substantially, the dose may be reduced to 1 or 2 grams 3 times a day to improve gastrointestinal tolerance (Prod Info Radiogardase(TM), 2003).

**2)** If swallowing large numbers of capsules is not tolerated, capsules may be opened and mixed with bland food or liquids. However, breaking open the capsules will cause the mouth and teeth to become blue during the time of treatment. May be taken with food to stimulate excretion of cesium or thallium (Prod Info Radiogardase(TM), 2003).

**3)** Lactulose, sorbitol, or mannitol may be added to insoluble **Prussian** blue to prevent obstipation (Thompson & Callen, 2004; Thompson & Church, 2001; Malbrain et al, 1997). A high fiber diet is recommended (Blanusa et al, 2005).

**B)** CESIUM POISONING

**1)** ADULTS AND ADOLESCENTS 13 YEARS OF AGE OR OLDER - 3 grams orally three times a day. Optimal duration of therapy is not established. Monitor electrocardiogram for resolution of QTc interval prolongation to determine the need for continued therapy. The dose may be reduced to 1 or 2 grams three times a day to improve gastrointestinal tolerance in patients requiring prolonged treatment (Prod Info Radiogardase(TM), 2003).

**2)** If swallowing large numbers of capsules is not tolerated, capsules may be opened and mixed with bland food or liquids (Prod Info Radiogardase(TM), 2003). Breaking open the capsules will cause the mouth and teeth to become blue during the time of treatment. May be taken with food to stimulate excretion of cesium or thallium.

**3)** Lactulose, sorbitol, or mannitol may be added to insoluble **Prussian** blue to prevent obstipation

(Thompson & Callen, 2004; Thompson & Church, 2001; Malbrain et al, 1997). A high fiber diet is recommended (Blanusa et al, 2005).

**C)** THALLIUM POISONING

**1)** ADULTS AND ADOLESCENTS 13 YEARS OF AGE OR OLDER - 3 grams orally three times a day. Optimal duration of therapy is not established. Monitor urinary thallium concentration to determine the need for continued therapy; some authors recommend continuing therapy until urinary thallium elimination is below 0.5 milligram/day (Hoffman, 2003). The dose may be reduced to 1 or 2 grams 3 times a day to improve gastrointestinal tolerance in patients requiring prolonged treatment (Prod Info Radiogardase(TM), 2003).

**2)** If swallowing large numbers of capsules is not tolerated, capsules may be opened and mixed with bland food or liquids. However, breaking open the capsules will cause the mouth and teeth to become blue during the time of treatment. May be taken with food to stimulate excretion of thallium (Prod Info Radiogardase(TM), 2003).

**3)** Lactulose, sorbitol, or mannitol may be added to insoluble **Prussian** blue to prevent obstipation (Thompson & Callen, 2004; Thompson & Church, 2001; Malbrain et al, 1997). A high fiber diet is recommended (Blanusa et al, 2005).

**7.2.2** PEDIATRIC

**A)** RADIOACTIVE CESIUM OR THALLIUM

**1)** CHILDREN (2 TO 12 YEARS) - 1 gram orally three times a day; treatment should be initiated as soon as possible after contamination is suspected, and should be continued for a minimum of 30 days, and continued thereafter based on the level of contamination and the judgment of the clinician. Administration of a laxative may be required to prevent obstipation. Safety and efficacy of insoluble **Prussian** infants and neonates have not been established (Prod Info Radiogardase(TM), 2003).

**2)** If swallowing large numbers of capsules is not tolerated, capsules may be opened and mixed with bland food or liquids. However, breaking open the capsules will cause the mouth and teeth to become blue during the time of treatment. May be taken with food to stimulate excretion of cesium or thallium (Prod Info Radiogardase(TM), 2003).

**B)** CESIUM POISONING

**1)** There are no reported cases of the use of **Prussian** blue in a child for the treatment of cesium poisoning.

**C)** THALLIUM POISONING

**1)** CHILDREN (2 TO 12 YEARS) - 1 gram orally three times a day. Optimal duration of therapy is not established. Monitor urinary thallium concentration to determine the need for continued therapy; some authors recommend continuing therapy until urinary thallium elimination is below 0.5 milligram/day (Hoffman, 2003). Administration of a laxative may be required to prevent obstipation. Safety and efficacy of insoluble **Prussian** blue in infants and neonates patients have not been established (Prod Info Radiogardase(TM), 2003).

**2)** If swallowing large numbers of capsules is not tolerated, capsules may be opened and mixed with bland food or liquids. However, breaking open the capsules will cause the mouth and teeth to become blue during the time of treatment. May be taken with food to stimulate excretion of thallium (Prod Info Radiogardase(TM), 2003).

## 7.4 MAXIMUM TOLERATED EXPOSURE

**A)** Doses up to 10 grams/day have been well tolerated (Thompson & Church, 2001). Doses of 20 grams/day have been used previously(Thompson & Callen, 2004).

## 7.6 WORKPLACE STANDARDS

**A)** ACGIH TLV Values for CAS14038-43-8 (American Conference of Governmental Industrial Hygienists, 2010):

**1)** Not Listed

**B)** NIOSH REL and IDLH Values for CAS14038-43-8 (National Institute for Occupational Safety and Health, 2007):

**1)** Not Listed

**C)** Carcinogenicity Ratings for CAS14038-43-8 :

**1)** ACGIH (American Conference of Governmental Industrial Hygienists, 2010): Not Listed

**2)** EPA (IRIS, 2004): Not Listed
**3)** IARC (IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2006; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2007; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2010a; IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2008; IARC, 2004): Not Listed
**4)** NIOSH (National Institute for Occupational Safety and Health, 2007): Not Listed
**5)** MAK (DFG, 2002): Not Listed
**6)** NTP (NTP, 2005): Not Listed

**D)** OSHA PEL Values for CAS14038-43-8 (29 CFR 1910.1000, 2006):
**1)** Not Listed

## 7.7 TOXICITY INFORMATION

**7.7.1** TOXICITY VALUES

**A)** LD50- (INTRAPERITONEAL)MOUSE:
**1)** 2 g/kg; toxic effects: somnolence, dyspnea (RTECS, 2003).

**B)** LD50- (INTRAPERITONEAL)RAT:
**1)** 2100 mg/kg; toxic effects: somnolence, dyspnea (RTECS, 2003)

# 8.0 KINETICS

ABSORPTION

METABOLISM

EXCRETION

## 8.1 ABSORPTION

**A)** THERAPEUTIC
**1)** Following an oral ingestion, insoluble **Prussian** blue is negligibly absorbed through the intact gastrointestinal tract (Prod Info Radiogardase(TM), 2003).
**2)** Bioavailability - oral, 1% or less; after a single dose of 40 mg of labeled insoluble **Prussian** to pigs, 99% of the dose was excreted in the feces (Prod Info Radiogardase(TM), 2003).

## 8.3 METABOLISM

**8.3.1** METABOLISM SITES AND KINETICS

**A)** WITH THERAPEUTIC USE
**1)** Approximately 7% of **Prussian** blue is metabolized to cyanoferrate, which may also bind thallium (Prod Info Radiogardase(TM), 2003).
**2)** Release of cyanide from **Prussian** blue in normal situations is minimal (<0.1% calculated and observed). Cyanide release was calculated between 1.6 and 2.9 mg/24 hours given a dose of 20 grams and a gastrointestinal transit time of 24 hours (Verzijl et al, 1993). In three male volunteers, 2 milligrams of non-complex bound cyanide (0.03 mg cyanide/kg) were absorbed from 500 mg oral potassium ferric hexacyanoferrate(II), a factor of 20-100 below the lethal dose in humans (Nielsen et al, 1990). Cyanide release is enhanced by low pH, and exposure might be increased in conditions such as Zollinger-Ellison syndrome or gastrinemia (Thompson & Callen, 2004).

## 8.4 EXCRETION

**8.4.2** FECES

**A)** Elimination of **Prussian** blue is predominantly fecal; after a single dose of 40 mg of labeled insoluble **Prussian** blue was given to pigs, 99% of the dose was excreted in the feces (Prod Info Radiogardase(TM),

2003).

## 9.0 PHARMACOLOGY/TOXICOLOGY

### 9.1 PHARMACOLOGIC MECHANISM

**A)** Insoluble **Prussian** blue acts via ion-exchange, adsorption, and mechanical trapping within its crystal structure, and has a very high affinity for radioactive and non-radioactive cesium and thallium. Following oral administration, it is negligibly absorbed by the gastrointestinal tract. Insoluble **Prussian** blue binds ingested cesium and thallium isotopes in the GI tract, reducing absorption. Cesium and thallium isotopes excreted in bile are also bound, limiting reabsorption via enterohepatic circulation. This changes the primary route of isotope elimination from renal to fecal, and increases the rate of elimination of these isotopes (Prod Info Radiogardase(TM), 2003). It has also been reported that potassium is exchanged for cesium on the surface of the crystal lattice (Thompson & Callen, 2004). **Prussian** blue with a smaller crystal size has both higher adsorption capacity and antidotal efficacy for thallium (Kravzov et al, 1993).

**B)** Two different forms of **Prussian** blue exist – 'soluble' (colloidal) and insoluble (non-colloidal). Insoluble **Prussian** blue has been most widely used in human radioactive cesium poisoning. In vitro studies found that Insoluble **Prussian** blue had three times the binding capacity of soluble **Prussian** blue at pH 7.5 (optimal pH for cesium-137 adsorption). In vivo experiments showed that soluble **Prussian** blue broke down to an unbound form which complexed with cesium and was incapable of excretion (Thompson & Callen, 2004). Another in vivo study showed a slight superiority to soluble **Prussian** blue (Dresow et al, 1993). Soluble **Prussian**
majority of human thallium cases in a recent review, and it seems to be more effective for thallium poisoning, possibly because of its higher potassium concentration (Hoffman, 2003; Thompson & Callen, 2004).

**C)** CESIUM TOXICITY

**1)** Non-radioactive cesium chloride is used as an alternative therapy by cancer patients (Pinter et al, 2002; Thurgur et al, 2006). Radioactive cesium is a primary component of radioactive fallout, radioactive waste, radiotherapy devices, mining and milling of pollucite, and nuclear power plant operations. The physical half-life of cesium-137 (Cs-137) is approximately 30 years, and that of cesium-134 (Cs-134) is 2 years, making both isotopes a long-term radiological hazard (Agency for Toxic Substances and Disease Registry, 2004). Cesium contamination may occur via ingestion, inhalation, or dermal penetration.

**a)** High levels of non-radioactive cesium are arrythmogenic and may produce prolongation of the QTc interval and torsades de pointes (Pinter et al, 2002).

**2)** Once absorbed, radioactive cesium follows the same biochemical pathways as potassium. The biological and effective half-life of Cs-137 is 110 days. It is uniformly distributed, with higher concentrations in the liver, skeletal muscle, and erythrocytes. Dermal exposure causes conditions ranging from mild skin irritation to necrotizing lesions. Gastrointestinal complaints are common, including severe nausea, vomiting and diarrhea. Eventually, bone marrow depression occurs, leading to infection, hemorrhage, and death. It is well absorbed orally, and is eliminated primarily through the kidneys. Cs-137 crosses the placenta, and yielded a neonatal Cs-137 concentration at birth identical to that of a mother exposed during her 4th month of pregnancy (Prod Info Radiogardase(TM), 2003). Cesium can be found in the breast milk of mothers with an internal cesium burden(Agency for Toxic Substances and Disease Registry, 2004).

**3)** Since Insoluble **Prussian** blue binds cesium in the gastrointestinal tract, systemic exposure is significantly decreased and fecal excretion is increased (Prod Info Radiogardase(TM), 2003; Thompson & Callen, 2004).

**4)** According to the manufacturer's data, 65 patients and 7 normal human volunteers received Insoluble **Prussian** blue in literature reports after internal contamination with Cs-137 (Prod Info Radiogardase(TM), 2003). A literature review by Thompson and Callen (2004) noted 83 patients and 3 human volunteers (Thompson & Callen, 2004).

**a)** In the 1987 incident in Goiania, Brazil, 46 patients were extensively contaminated with internal Cs-137. Insoluble **Prussian** blue treatment (doses up to 10 grams/day) reduced the mean whole-body half-life of Cs-137 by 69% in adults, 46% in adolescents, and 43% in children (Prod Info Radiogardase(TM), 2003).

**b)** In 2 human volunteers, pretreatment with 1 gram Insoluble **Prussian** blue reduced absorption of food contaminated with Cs-134 in by 93.6% (Dresow et al, 1993).

**D)** THALLIUM TOXICITY

**1)** Non-radioactive thallium is used in industry and as a rodenticide. Environmental release occurs from coal combustion, cement plants, and smelting operations. Radioactive Thallium-201 (Tl-201) is widely used medically as a diagnostic agent in myocardial scintigraphy. Thallium-205 (Tl-205) has been used in nuclear

magnetic resonance research.
**2)** Thallium is rapidly and completely absorbed from either the gastrointestinal or respiratory tract, or through the skin. Water-soluble thallium salts are widely distributed into organs and tissues, including the brain, heart, kidney, skeletal muscle, and testis, which are the principal targets of thallium toxicity. Thallium freely crosses the placenta and may produce fetal toxicity, abnormalities, and demise (Hoffman, 2003). Alopecia and nail growth abnormalities, gastrointestinal distress and constipation, and painful sensory and motor neuropathies may occur (Andersen, 1984; Moore et al, 1993; Mulkey & Oehme, 1993). Due to the similarity of its charge and ionic radius to potassium, thallium distributes in the same manner, and may disrupt potassium-dependent and sulfhydryl-dependent functions, including those required for energy production and utilization (Hoffman, 2003; Moore et al, 1993; Mulkey & Oehme, 1993).
**3)** In data provided by the manufacturer, 34 patients with non-radioactive thallium poisoning treated with Insoluble **Prussian** blue were reported in the literature. In these cases, the drug reduced the mean serum biologic half-life of thallium from 8 days to 3 days (Prod Info Radiogardase(TM), 2003).
**4)** In a small case series, 11 patients with thallium intoxication were successfully treated with after ingesting various amounts of thallium. Patients presented from 1 to 151 days after thallium exposure, and all had classic symptoms of thallium poisoning to varying degrees. After 3 to 20 days of therapy, resolution of symptoms was observed, and elimination of thallium excretion in urine, feces, and blood was noted (Stevens et al, 1974). Other similar cases of the use of **Prussian** blue following thallium exposure have been reported (Pau, 2000; Atsmon et al, 2000; Malbrain et al, 1997; Pai, 1987; Ghezzi & Bozza Marrubini, 1979).
**5)** Adsorption of Tl-201 to **Prussian** blue is a pH-dependent process, with the most uptake at pH 8 (Bhardwaj et al, 2006).
**6)** In one patient, **Prussian** blue reduced whole body radioactivity from Tl-201 myocardial scintigraphy by 30% at 48 hours compared to no **Prussian** blue treatment (Bhardwaj et al, 2006).

## 10.0 PHYSICOCHEMICAL

PHYSICAL CHARACTERISTICS

MOLECULAR WEIGHT

### 10.1 PHYSICAL CHARACTERISTICS
**A)** Insoluble **Prussian** blue (ferric(III) hexacyanoferrate(II)) is a cubic lattice with the Fe(II) and Fe(III) atoms occupying the corners of the cube and the cyanide groups positioned on the sides. The may be uniformly fine, dark granules or coarse light and dark-colored granules (Prod Info Radiogardase(TM), 2003).

### 10.3 MOLECULAR WEIGHT
**A)** 859.3 (Prod Info Radiogardase(TM), 2003)

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