HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BAL in Oil safely and effectively. See full prescribing information for BAL in Oil.

BAL in Oil (dimercaprol injection), for intramuscular use
Initial U.S. Approval: 1946

----------INDICATIONS AND USAGE----------

BAL in Oil is a metal chelating agent indicated for the treatment of adult and pediatric patients with:

- Arsenic or gold poisoning. (1)
- Acute mercury poisoning within 2 hours following ingestion. (1)
- Acute lead poisoning when used concomitantly with edetate calcium disodium. (1)

Limitations of Use

- BAL in Oil is not effective and should not be used for chronic mercury poisoning. (1)
- BAL in Oil is not effective and should not be used for chronic lead poisoning. (1)
- BAL in Oil is not effective and should not be used for poisoning caused by other heavy metals such as antimony and bismuth. (1)
- BAL in Oil is not indicated for use in iron, cadmium, or selenium poisoning because the resulting dimercaprol-metal complexes are more toxic than the metal alone, especially to the kidneys. (1)

----------DOSAGE AND ADMINISTRATION----------

- Administer as deep intramuscular injection only (2).

Indication	Recommended Dosage
Mild arsenic or gold poisoning	2.5 mg/kg four times daily for two days, twice on Day three; once daily for ten days thereafter. (2.1)
Severe arsenic or gold poisoning	3 mg/kg every four hours for two days, four times on Day three, twice daily for ten days thereafter. (2.1)
Mercury poisoning	5 mg/kg initially, then 2.5 mg/kg one to two times daily for ten days. (2.1)
Acute lead poisoning	4 mg/kg given alone for the first dose, thereafter 3 mg/kg every four hours in combination with Edetate Calcium Disodium Injection administered at a separate site. Maintain treatment for two to seven days depending upon clinical response. (2.1)
Acute lead encephalopathy	4 mg/kg given alone for the first dose, thereafter 4 mg/kg every four hours in combination with Edetate Calcium Disodium Injection administered at a separate site; reduce to 3 mg/kg after first dose in less severe cases; treat two to seven days based on clinical response. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------

Injection: 300 mg/3 mL (100 mg/mL) single-dose ampule (3)

----------CONTRAINDICATIONS----------

- Patients with peanut allergies: Due to peanut oil in the formulation use of BAL in Oil presents the risk of serious hypersensitivity reactions. (4)
- Most cases of hepatic insufficiency, except postarsenical jaundice. (4)
- Iron products: Contraindicated with concomitant use of BAL in Oil. (4)

----------WARNINGS AND PRECAUTIONS----------

- Renal Toxicity: May cause acute renal injury, particularly with prolonged use or doses >3 mg/kg. Assess renal function before and during treatment. Discontinue if renal insufficiency develops. (5.1)
- Risk of Hypersensitivity Reactions in Peanut Allergic Patients: Screen patients for allergy to peanuts. Monitor for signs or symptoms of hypersensitivity reaction. (5.2)
- Injection Site Reaction: May cause pain, swelling, or sterile abscess. Administer as a deep intramuscular injection only. (5.3)
- Risk of Hemolytic Anemia in Patients with Glucose 6-phosphate Dehydrogenase Deficiency: May cause severe hemolysis in patients with G6PD deficiency. Screen high-risk patients and discontinue if hemolysis occurs. (5.4)
- Fever in Pediatric Patients: Fever has been reported in pediatric patients and may persist during treatment. Evaluate persistent or high fever for other causes. (5.5)

----------ADVERSE REACTIONS----------

Most common adverse reactions are local pain at site of injection and rise in blood pressure accompanied by tachycardia. (6)

To report SUSPECTED ADVERSE REACTIONS, contact PROVEPHARM Inc at 1–833-727-6556 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Iron products: Concomitant use with BAL in Oil is contraindicated. Concomitant use with BAL in Oil can cause severe renal toxicity (7.1)

----------USE IN SPECIFIC POPULATIONS----------

Pediatric Use: Consider premedication with H1 antihistamine. (8.4)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

BAL in Oil is a metal chelating agent indicated for the treatment of adult and pediatric patients with:

- Arsenic or gold poisoning
- Acute mercury poisoning within 2 hours following ingestion
- Acute lead poisoning when used concomitantly with edetate calcium disodium

Limitations of Use

- BAL in Oil is not effective and should not be used for chronic mercury poisoning.
- BAL in Oil is not effective and should not be used for chronic lead poisoning.
- BAL in Oil is not effective and should not be used for poisoning caused by other heavy metals such as antimony and bismuth.
- BAL in Oil is not indicated for use in iron, cadmium, or selenium poisoning because the resulting dimercaprol-metal complexes are more toxic than the metal alone, especially to the kidneys.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Initiate treatment early.

Administer BAL in Oil by deep intramuscular injection only.

Indication	Recommended Dosage for Adult and Pediatric Patients
Mild arsenic or gold poisoning	2.5 mg/kg four times daily for two days, two times on the third day, and once daily thereafter for ten days
Severe arsenic or gold poisoning	3 mg/kg every four hours for two days, four times on the third day, then twice daily thereafter for ten days.
Mercury poisoning	5 mg/kg initially, followed by 2.5 mg/kg one or two times daily for ten days
Acute lead poisoning	4 mg/kg given alone for the first dose, thereafter 3 mg/kg every four hours in combination with Edetate Calcium Disodium Injection administered at a separate site. Maintain treatment for two to seven days depending upon clinical response.
Acute lead encephalopathy	4 mg/kg given alone for the first dose, thereafter 4 mg/kg every four hours in combination with Edetate Calcium Disodium Injection administered at a separate site. Reduce to 3 mg/kg after first dose in less severe cases. Maintain treatment for two to seven days depending upon clinical response.

Use other supportive measures in conjunction with BAL in Oil therapy.

Monitor blood lead levels periodically after completion of initial therapy course.

2.2 Alkalinization of Urine During Treatment

Alkalinize the urine to protect the kidneys during BAL in Oil treatment. The dimercaprol-metal complex dissociates in acidic medium *[see Warnings and Precautions (5.1)]*.

2.3 Preparation and Administration

Pediatric patients may need premedication with an antihistamine (H1 antagonist) to reduce the risk of certain histamine-like adverse reactions.

BAL in Oil should be inspected visually for particulate matter and discoloration prior to administration. Advise patients that the injection will be painful.
Administer by deep intramuscular injection only.

3 DOSAGE FORMS AND STRENGTHS

Injection: 300 mg/3 mL (100 mg/mL) of dimercaprol as clear, colorless to pale yellow, oily solution, in an amber glass single-dose ampule.

4 CONTRAINDICATIONS

- BAL in Oil is contraindicated in patients with peanut allergies due to peanut oil in the formulation and the risk of serious hypersensitivity reactions *[see Warnings and Precautions (5.2)]*.
- BAL in Oil is contraindicated in patients with hepatic insufficiency, except in those with postarsenical jaundice.
- Concomitant use of BAL in Oil with iron-containing products or in patients with iron poisoning is contraindicated. The combination forms a toxic complex that can cause renal toxicity *[see Drug Interactions (7.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Renal Toxicity

BAL in Oil may cause renal toxicity, particularly with prolonged use or at higher doses. Renal toxicity may manifest as acute tubular necrosis, proteinuria, hematuria, increased BUN and serum creatinine, decreased creatinine clearance, oliguria (or anuria in severe cases). Patients with pre-existing renal impairment are at increased risk for worsening renal dysfunction during BAL in Oil treatment. Dehydration, concurrent use of other nephrotoxic agents, and the severity of heavy metal poisoning may further increase this risk. The concomitant use of iron products and BAL in Oil can also cause renal toxicity *[see Drug Interactions (7.1)]*. Assess renal function (serum creatinine, BUN, urinalysis) prior to initiating BAL in Oil. Monitor renal function frequently during treatment, particularly in patients receiving prolonged treatment or doses exceeding 3 mg/kg. Monitor for proteinuria and hematuria by urinalysis. Monitor fluid balance, maintain adequate hydration, and alkalinize the urine. If acute renal insufficiency develops during BAL in Oil treatment, consider discontinuation of treatment.

5.2 Risk of Hypersensitivity Reactions in Peanut Allergic Patients

BAL in Oil is contraindicated in patients with peanut allergies due to peanut oil in the formulation. Peanut oil may cause hypersensitivity reactions in some individuals. Screen all patients for a history of peanut allergy before initiating treatment with BAL in Oil. Medication and equipment necessary to treat hypersensitivity reactions should be available if the product is administered to peanut-allergic patients. Monitor patients for signs and symptoms of hypersensitivity reactions during and following administration, particularly during the first dose. Signs and symptoms may include urticaria, angioedema, bronchospasm, and hypotension.

5.3 Injection Site Reactions

BAL in Oil may cause injection site reactions. The symptoms may include pain, redness, or swelling at the injection site. Occasionally, a painful, sterile abscess may develop at the injection site. Use different injection sites for concurrent medications (e.g., with Edetate Calcium Disodium Injection for lead poisoning). Ensure that BAL in Oil is administered as a deep intramuscular injection only. Apply local warm compresses and analgesics if mild pain or swelling occurs.

5.4 Risk of Hemolytic Anemia in Patients with Glucose 6-phosphate Dehydrogenase Deficiency

Use of BAL in Oil may induce hemolysis, including severe and life-threatening forms of hemolytic anemia in patients with glucose 6-phosphate dehydrogenase (G6PD) deficiency. Screen high-risk patients for G6PD deficiency before initiating therapy with BAL in Oil. Populations at increased risk include those of African, Mediterranean, or Southern Asian ancestry. Consider alternative chelating agents if available and appropriate for the specific metal poisoning being treated. If BAL in Oil must be used in patients with known or suspected G6PD deficiency, monitor carefully for clinical signs of a hemolytic crisis. Symptoms of hemolysis include dark or "tea colored" urine, jaundice/scleral icterus, an acute drop in hemoglobin or hematocrit, fatigue, dizziness, or shortness of breath. If acute hemolysis occurs, discontinue BAL in Oil immediately. Blood transfusions or exchange transfusions may be required.

5.5 Fever in Pediatric Patients

Fever occurs in about 30% of pediatric patients treated with BAL in Oil. The onset is most common after the second or third dose. Once it develops, it may persist for the duration of BAL in Oil treatment. If the fever is persistent or very high, evaluate for other causes.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Renal Toxicity *[see Warnings and Precautions (5.1)]*
- Risk of Hypersensitivity Reactions in Peanut Allergic Patients *[see Warnings and Precautions (5.2)]*
- Injection Site Reaction *[see Warnings and Precautions (5.3)]*
- Risk of Hemolytic Anemia in Patients with Glucose 6-phosphate Dehydrogenase Deficiency *[see Warnings and Precautions (5.4)]*
- Fever in Pediatric Patients *[see Warnings and Precautions (5.5)]*

The following adverse reactions associated with the use of BAL in Oil were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Local injection site pain
- Fever (especially in pediatric patients)
- Tachycardia
- Reduction in polymorphonuclear leukocytes
- elevated blood pressure

7 DRUG INTERACTIONS

7.1 Iron Products

The use of iron products with BAL in Oil is contraindicated. Concomitant use of BAL in Oil with iron-containing products or in patients with iron poisoning may result in the formation of toxic metal-dimercaprol chelates, which can cause severe renal toxicity. If iron products are needed in a patient who has taken BAL in Oil, wait at least 24 hours after the last dose of BAL in Oil before starting or resuming iron-containing products.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on BAL in Oil use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with BAL in Oil.

The estimated background risk of major birth defects and miscarriage for the indicated population(s) is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

There is no data on the presence of dimercaprol or its metabolite in human milk, the effects on the breastfed child, or the effects on milk production.

8.4 Pediatric Use

The safety and effectiveness of BAL in Oil have been established in pediatric patients with arsenic or gold poisoning, acute mercury poisoning within 2 hours following ingestion, and acute lead poisoning when used concomitantly with edetate calcium disodium. Consider premedication of pediatric patients with H1 antihistamine *[see Dosage and Administration (2.3)]*.

8.6 Renal Impairment

Do not use in patients with acute renal failure or oliguria/anuria. If acute renal insufficiency develops during BAL in Oil treatment, consider discontinuation of treatment *[see Warnings and Precautions (5.1)]*.

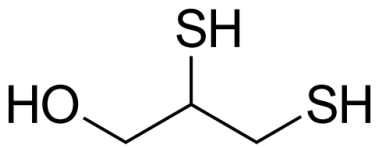
10 OVERDOSAGE

Overdosage exceeding 5 mg/kg may result in nausea, vomiting, headache, burning sensation in the lips, mouth, and throat, tightness or pain in the throat, chest or hands, ocular changes (conjunctivitis, lacrimation, and blepharal spasm), rhinorrhea, salivation, tingling of hands, burning sensation in the penis, diaphoresis, abdominal pain, convulsions, and stupor, beginning within 30 minutes and subsiding within 6 hours following injection. Antihistamine may be tried for relief of the symptoms associated with overdosage. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11 DESCRIPTION

BAL in Oil (dimercaprol injection, USP) is a sterile, clear, colorless to pale yellow, oily solution of dimercaprol, a chelating agent, with a characteristic mercaptan-like odor. Each 1 mL sterile BAL in Oil (dimercaprol injection USP) contains: 100 mg dimercaprol in 200 mg benzyl benzoate and 700 mg peanut oil.

The chemical name of dimercaprol is 2,3-dimercapto-1-propanol. Its molecular formula is $C_3H_8OS_2$ and its molecular weight is 124.22 g/mol. Its structural formula is:



Dimercaprol

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dimercaprol is a metal chelator that binds to heavy metals (arsenic, gold, inorganic mercury, and in combination therapy, lead) and forms stable, water-soluble complexes that can be excreted from the body.

12.3 Pharmacokinetics

Absorption

Following deep intramuscular injection, dimercaprol is rapidly absorbed, reaching peak plasma concentrations within 30 to 60 minutes.

Distribution

Dimercaprol is highly lipophilic and distributes widely throughout the body, including the intracellular space. It reaches high concentrations in the liver, kidneys, and brain.

Metabolism & Excretion

Unbound dimercaprol is metabolized in the liver via glucuronidation into inactive metabolites. Both the metabolites and the metal-dimercaprol complexes are primarily excreted in the urine, with a small portion eliminated via bile.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

The intramuscular LD50 in rats is approximately 105 mg/kg; intraperitoneally 140 mg/kg. The intraperitoneal LD80 in mice is approximately 125 mg/kg.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

BAL in Oil (dimercaprol injection, USP) 300 mg/3 mL (100 mg/mL) is supplied in a carton of 10 single-dose 3 mL glass ampules. (NDC 81284-197-03).

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F); [See USP Controlled Room Temperature].
Use immediately after opening ampule. Discard unused portion.

17 PATIENT COUNSELING INFORMATION

Risk of Hypersensitivity Reactions in Peanut Allergic Patients

Advise the patient that BAL in Oil contains peanut oil and is contraindicated in patients with peanut allergy. Instruct the patient to seek immediate medical attention if signs or symptoms of a hypersensitivity reaction occur, including difficulty breathing, swelling of the face, lips, tongue, or throat, hives, rash, itching, dizziness, fainting, or hypotension *[see Contraindications (4) and Warnings and Precautions (5.2)].*

Renal Toxicity

Advise the patient that BAL in Oil may cause kidney injury. Inform the patient to report decreased

urine output, swelling, unusual fatigue, or dark or bloody urine. Explain that kidney function will be monitored during treatment *[see Warnings and Precautions (5.1)].*

Hemolytic Anemia in Patients with G6PD Deficiency
Advise patients, particularly those of African, Mediterranean, or Southern Asian ancestry, that BAL in Oil may cause hemolysis if they have glucose-6-phosphate dehydrogenase (G6PD) deficiency. Instruct patients to report symptoms such as dark or "tea-colored" urine, yellowing of the skin or eyes, fatigue, shortness of breath, or dizziness. Inform patients that treatment may be discontinued if hemolysis occurs *[see Warnings and Precautions (5.4)].*

Iron-Containing Products
Advise the patient not to take iron-containing products during treatment with BAL in Oil unless directed by a healthcare provider. Explain that concomitant use may cause serious kidney toxicity *[see Contraindications (4) and Drug Interactions (7.1)].*

Injection Site Reactions
Inform the patient that BAL in Oil is administered as a deep intramuscular injection and that pain at the injection site is common. Advise the patient to report severe or persistent pain, swelling, or redness at the injection site *[see Warnings and Precautions (5.3)].*

Fever in Pediatric Patients
Inform caregivers that fever may occur in pediatric patients during treatment and may begin after the second or third dose. Advise caregivers to notify the healthcare provider if fever is persistent or very high, as other causes may need to be evaluated *[see Warnings and Precautions (5.5)].*

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