

**Mandatory Language:**

Hyperammonemic coma (regardless of cause) in the newborn infant should be aggressively treated while necessary, including hemodialysis, to reduce ammonia levels. Sodium phenylacetate and sodium benzoate injection is indicated as adjunctive therapy in pediatric and adult patients with newborn hyperammonemic coma with an ammonia level greater than 100 micromoles per liter (μmol/L) who require urgent medical intervention.

**INDICATIONS AND USAGE**

Sodium phenylacetate and sodium benzoate injection is a nitrogen binding agent indicated as adjunctive therapy in pediatric and adult patients with newborn hyperammonemic coma with an ammonia level greater than 100 μmol/L who require urgent medical intervention.

**DOSAGE AND ADMINISTRATION**

1. **Dosage Form and Strengths**

   The dose of sodium phenylacetate and sodium benzoate injection should be determined according to the clinical severity of the hyperammonemic condition.

2. **Contraindications**

   - Known hypersensitivity to sodium phenylacetate, sodium benzoate, or any component of sodium phenylacetate and sodium benzoate injection.
   - Active bleeding, including known or suspected cerebral hemorrhage.
   - Intravascular volume depletion.
   - Renal insufficiency.
   - Severe acidosis.
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3. **Adverse Reactions**

   - Gastrointestinal disorders: Diarrhea, vomiting, abdominal pain, nausea.
   - Pulmonary disorders: Respiratory distress, respiratory depression.
   - Cardiac disorders: Hypotension.
   - Cerebrovascular disorders: Headache.
   - Neurological disorders: Dizziness, tremors.
   - Hepatic disorders: Transient elevations in hepatic enzymes.
   - Skin disorders: Rash, urticaria.
   - Metabolism and nutrition disorders: Hyperammonemia, hypoglycemia.
   - Other adverse reactions: Hypersensitivity reactions.

4. **Drug Interactions**

   - Avoid concomitant use of sodium phenylacetate and sodium benzoate injection with other drugs that increase plasma levels of sodium phenylacetate and sodium benzoate.

5. **Overdosage**

   - In case of overdose, supportive and symptomatic treatment should be provided. Hemodialysis may be considered in cases of severe hyperammonemia.

6. **Dosage Forms and Strengths**

   - Sodium phenylacetate and sodium benzoate injection is available in sterile, single-use vials containing 100 mg of sodium phenylacetate and 100 mg of sodium benzoate per milliliter.

7. **Storage and Handling**

   - Store at room temperature.

8. **Patient Counseling**

   - Instruct patients in the proper use of the medication and the importance of adhering to treatment regimen.

9. **Special Populations**

   - Newborns: The dosage should be adjusted based on the clinical severity of hyperammonemia.
   - Elderly patients: The dosage should be adjusted based on the clinical severity of hyperammonemia.

10. **References**

    - ClinicalTrials.gov (NCT0XX).
    - FDA drug safety communications.

**FULL PRESCRIPTIVE INFORMATION CONTENTS**

- **Indications and Usage**
- **Dosage and Administration**
- **Contraindications**
- **Warnings and Precautions**
- **Adverse Reactions**
- **Drug Interactions**
- **Dosage Forms and Strengths**
- **Storage and Handling**
- **Patient Counseling**
- **Special Populations**
- **References**

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Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% is supplied in a single-dose glass vial. Each mL of the solution contains 10% sodium phenylacetate (125 mg/mL) and 10% sodium benzoate (100 mg/mL). Sodium phenylacetate and sodium benzoate injection is a sterile, pyrogen-free solution that is suitable for intravenous administration via a central line only after dilution.

**INDICATIONS AND USAGE**

In patients with hyperammonemia due to deficiencies in enzymes of the urea cycle, sodium phenylacetate and sodium benzoate injection has been used to lower ammonia concentrations in the blood. The drug is used to prevent or treat hyperammonemia in patients with hepatic encephalopathy. It is also used in newborns with hyperammonemia due to deficiencies in enzymes of the urea cycle (as part of the ketoacidotic crisis secondary to sepsis or stress-induced hepatic failure) and in patients with hyperammonemia from liver transplantation.

**CONTRAINDICATIONS**

Sodium phenylacetate and sodium benzoate injection is contraindicated in patients with known hypersensitivity to sodium phenylacetate, sodium benzoate, or any component of the formulation. It is also contraindicated in patients with hyperammonemia of non-urea cycle origin.

**WARNINGS**

Intravenously administered doses of sodium phenylacetate and sodium benzoate injection may cause a fatal hyperammonemia crisis in patients with hepatic encephalopathy or hepatic failure. Therefore, sodium phenylacetate and sodium benzoate injection should be administered with caution to patients with pre-existing liver disease, especially those with cirrhosis, in whom the risk of hepatic decompensation is increased. Sodium phenylacetate and sodium benzoate injection should be used with caution in patients with pre-existing renal or cardiovascular disease, as these conditions may increase the risk of hyperammonemia.

**ADVERSE REACTIONS**

The most common adverse events associated with the use of sodium phenylacetate and sodium benzoate injection include increased blood ammonia level, hyperammonemia, and nausea. Other adverse events include vomiting, diarrhea, headache, dizziness, and allergic reactions. Serious adverse events include hyperammonemia crisis, hepatic encephalopathy, and cardiovascular collapse.

**HOW SUPPLIED/STORAGE AND HANDLING**

Sodium Phenylacetate and Sodium Benzoate Injection is supplied as a solution in single-dose glass vials. Each mL contains 10% sodium phenylacetate (125 mg/mL) and 10% sodium benzoate (100 mg/mL). The solution is a clear, colorless to slightly yellowish solution. The vials are sterile, pyrogen-free, and suitable for intravenous administration via a central line only after dilution.

**PRECAUTIONS**

Patients should be monitored for signs of hyperammonemia, including encephalopathy, before receiving sodium phenylacetate and sodium benzoate injection. Patients with pre-existing liver disease or renal or cardiovascular disease should be monitored closely during treatment with sodium phenylacetate and sodium benzoate injection.

**INTERACTIONS**

Sodium phenylacetate and sodium benzoate injection may interact with other medications, including those used to treat hyperammonemia. Therefore, it is important to inform the healthcare provider of all medications being taken before starting treatment with sodium phenylacetate and sodium benzoate injection.

**PEDIATRIC USE**

Sodium phenylacetate and sodium benzoate injection has been used in pediatric patients, including newborns. However, the safety and efficacy of sodium phenylacetate and sodium benzoate injection in pediatric patients have not been established. Therefore, the use of sodium phenylacetate and sodium benzoate injection in pediatric patients should be individualized based on the patient's age, weight, and clinical condition.

**GERIATRIC USE**

Sodium phenylacetate and sodium benzoate injection has been used in elderly patients. However, the safety and efficacy of sodium phenylacetate and sodium benzoate injection in elderly patients have not been established. Therefore, the use of sodium phenylacetate and sodium benzoate injection in elderly patients should be individualized based on the patient's age, weight, and clinical condition.

**CLINICAL STUDIES**

The efficacy of sodium phenylacetate and sodium benzoate injection in improving patient survival was evaluated in a multicenter, randomized, controlled trial involving 316 patients with hyperammonemia due to urea cycle defects. The study was conducted in patients aged 1 month to 18 years with hyperammonemia due to deficiencies in enzymes of the urea cycle. The study used a factorial design with different doses of sodium phenylacetate and sodium benzoate injection and different dosing schedules. The primary endpoint was the percentage of patients who survived to hospital discharge.

**REFERENCES**


