Storage: Store at 25°C (77°F), excursions permitted to 15° - 30°C (59° - 89°F).

Keep out of the reach of children.

Marketed by: Trigen Laboratories, LLC
Sayreville, NJ 08872

Dosage: See accompanying package insert.

Each mL of Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% contains:
100 mg of sodium phenylacetate and 100 mg of sodium benzoate, and water for injection. Sodium hydroxide and/or hydrochloric acid may have been used for pH adjustment.

Sterile, concentrated solution must be diluted with sterile, dextrose injection, 10% (D10W) before intravenous administration.

Warning: Administration must be through a central line. Administration through a peripheral line may cause burns.

Must be diluted before IV administration.
Sodium Phenylacetate and Sodium Benzoate Injection 10%/10% 50 mL

Dosage: See accompanying package insert.

Each mL of Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% contains:
100 mg of sodium phenylacetate and 100 mg of sodium benzoate, and water for injection. Sodium hydroxide and/or hydrochloric acid may have been used for pH adjustment.

Sterile, concentrated solution must be diluted with sterile, dextrose injection, 10% (D10W) before intravenous administration.

Storage: Store at 25°C (77°F), excursions permitted to 15° - 30°C (59° - 86°F).

KEEP OUT OF THE REACH OF CHILDREN

Marketed by:
Trigen Laboratories, LLC
Sayreville, NJ 08872

Warning: Administration must be through a central line. Administration through a peripheral line may cause burns.

Must be diluted before IV administration
Sterile, non-pyrogenic, single-dose vial

For IV Use Only
Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% is a nitrogen binding agent indicated as adjunctive therapy in patients with acute metabolic acidosis, including those with hepatic encephalopathy, urea cycle disorders, and in the management of acute hyperammonemia in patients with liver failure. Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% should be administered intravenously for the relief of hyperchloremic acidosis, with or without concomitant hyperammonemia, in patients with acute liver failure. This agent is used for short-term therapy to transiently decrease plasma ammonia levels in patients who are unable to receive an alternative treatment. Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% should be administered by infusion over at least 10 to 12 hours. 

**Warnings and Precautions**
- Read the Patient Information before you use Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10%.
- Do not use this medicine if you are allergic to any of its ingredients.
- This medicine may cause side effects that may affect your ability to drive or operate machinery.
- This medicine may interact with other medications, so use it only as directed.
- Report any side effects to your doctor.

**Dosage and Administration**
- The recommended dosage of Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% is 1 g/m² body surface area per hour. Adjust the dosage based on clinical response and patient tolerance.
- The solution must be administered by infusion over at least 10 to 12 hours.
- Monitor the patient closely for signs of toxicity, including hyperventilation, metabolic acidosis, and hyperammonemia.
- Respiratory support and management of fluid overload may be necessary if necessary.

**Contraindications**
- Do not use this medicine if you have a known allergy to sodium phenylacetate or sodium benzoate.
- Do not use this medicine if you are pregnant or breastfeeding.

**Adverse Reactions**
- Common side effects include: headache, drowsiness, dizziness, nausea, and vomiting.
- Less common side effects include: hypotension, agitation, and fever.

**Interactions**
- This medicine may interact with other medications, so use it only as directed by your doctor.
- Report any side effects to your doctor.

**Precautions**
- Use caution when administering this medicine to patients with severe renal or hepatic impairment.
- Monitor the patient closely for signs of toxicity, including hyperventilation, metabolic acidosis, and hyperammonemia.

**Dosage Forms and Strengths**
- Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10% is available as 10% and 10% solutions.

**Drug Interactions**
- This medicine may interact with other medications, so use it only as directed.
- Report any side effects to your doctor.

**Reconstituted Solution**
- The reconstituted solution should be clear, colorless, and free from particulate matter.

**Numerical Tables**
- Table 1: Dosage and Administration
- Table 2: Adverse Reactions Occurring in ≥ 3% of Patients Treated with Sodium Phenylacetate and Sodium Benzoate Injection, 10%/10%
Sodium phenylacetate has a molecular weight of 133.15 and the molecular formula C7H7NO2. Sodium benzoate has a molecular weight of 122.12 and the molecular formula C7H6NO2.

Sodium phenylacetate and sodium benzoate are manufactured in such a way that it is highly unlikely that they could be linked to adverse reactions. However, it is not unknown that some reactions may occur.

**TABLE 3: Baseline Characteristics and Diagnoses of Study Population**

<table>
<thead>
<tr>
<th>Gender</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>310</td>
<td>150</td>
</tr>
</tbody>
</table>

**5.2 Receptor Interaction**

The binding of sodium phenylacetate to receptors is thought to be mediated by the sodium channel. This interaction is thought to be important in the regulation of sodium transport across the cell membrane.

**Figure 1**

Sodium phenylacetate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 2**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 3**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 4**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 5**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 6**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 7**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 8**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 9**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.

**Figure 10**

Sodium benzoate is a white, crystalline powder with a strong, offensive odor. It is soluble in water.