PENTOBARBITAL Sodium Injection, USP

URLS:
1 PENTOBARBITAL Sodium Injection, USP
2 Wholesaler Item Numbers:
3 Storage Requirements:
5 Product Photo 1:
6 Product Photo 2:
7 Product Photo 3:
8 All Photos
9 All Photos
10 Package Insert Page:

PDFS:
11 Package Insert
12 SDS/MSDS Sheet
13 Barcodes
14 Return Goods Policy
PENTOBARBITAL Sodium Injection, USP

Brand Name Equivalent: NEMBUTAL® (NEMBUTAL is a registered trademark of Oak Pharmaceutical)

Therapeutic Category: Sedative-Hypnotic/Anxiolytic

Available in:
- 1,000 mg per 20 mL multi-dose vials
- 2,500 mg per 50 mL multi-dose vials

Benefits:
- Preservative-free
- Not made with natural rubber latex

PreventIV Measures℠ Features:
- Easy-to-read drug name and dosage strength to aid in identifying the right product
- Bar codes included on the vial and carton for ease of scanning
- Unique label design to help products stand out on the shelf
- Enhanced packaging and labeling designed to promote safety and help reduce medication errors

Downloads:
- BAR CODES
- PACKAGE INSERT
- SDS SHEET
- WHOLESALER ITEM NUMBERS
- STORAGE REQUIREMENTS
- RETURN GOODS POLICY

NDC #25021 Description Strength Fill Volume Concentration Container Size Closure Unit of Sale

<table>
<thead>
<tr>
<th>NDC#</th>
<th>Description</th>
<th>Strength</th>
<th>Fill Volume</th>
<th>Concentration</th>
<th>Container Size</th>
<th>Closure</th>
<th>Unit of Sale</th>
</tr>
</thead>
<tbody>
<tr>
<td>676-20</td>
<td>Glass Vial</td>
<td>1,000 mg</td>
<td>20 mL</td>
<td>50 mg per mL</td>
<td>20 mL</td>
<td>20 mm</td>
<td>1</td>
</tr>
<tr>
<td>676-50</td>
<td>Glass Vial</td>
<td>2,500 mg</td>
<td>50 mL</td>
<td>50 mg per mL</td>
<td>50 mL</td>
<td>20 mm</td>
<td>1</td>
</tr>
</tbody>
</table>

Learn more about Sagent's position against the use of our products in capital punishment.
Sagent is dedicated to improving the outcomes of patients treated by licensed physicians, nurses, pharmacists and other healthcare professionals throughout the United States by supplying an extensive portfolio of injectable pharmaceutical products. In order to help ensure that patients have access to our products for use in accordance with the products’ labels but to ensure our products are not used in capital punishment, Sagent has implemented several contractual and distribution controls with its distributors and wholesalers to keep the sale of known components of lethal injection protocols from being sold to any prison pharmacy systems or other correctional facilities. In addition, Sagent does not accept orders from or sell into correctional facilities and prison pharmacy systems products believed to be part of certain states’ lethal injection protocols. Sagent is also committed to contacting the attorneys general and directors of departments of correction of the states that currently execute prisoners where it suspects its products could be used in a lethal injection.
PENTOBARBITAL Sodium Injection, USP

[Image of PENTOBARBITAL Sodium Injection, USP vials]
PENTOBARBITAL Sodium Injection, USP
Pentobarbital Sodium Injection, USP
Vials
DO NOT USE IF MATERIAL HAS PRECIPITATED

The barbiturates are nonselective central nervous system depressants which are primarily used as sedatives and also anticonvulsants in status epilepticus. The barbiturates and their sodium salts are subject to control under the Federal Controlled Substances Act (See "Drug Abuse and Dependence" section).

The sodium salts of semisynthetic, pentobarbital, phenobarbital, and secobarbital are available as sterile parenteral solutions.

The barbiturates are substituted pyrimidine derivatives in which the basic structure is common to these drugs, barbituric acid, a substance which has no central nervous system (CNS) activity. CNS activity is obtained by substituting alkyl, alkenyl, or alkynyl groups on the pyrimidine ring.

Pentobarbital Sodium Injection, USP is a sterile solution for intravenous or intramuscular injection. Each mL contains pentobarbital sodium 50 mg, in a vehicle of propylene glycol, 40%, alcohol, 10%, and water for injection, to render the pH adjusted to approximately 5.5 with hydrochloric acid and/or sodium hydroxide.

Pentobarbital Sodium Injection is a short-acting barbiturate, chemically designated as sodium 5-ethyl-5-(1-methylbutyl) barbiturate. The structural formula for Pentobarbital Sodium is:

\[
\text{Sodium 5-ethyl-5-(1-methylbutyl) barbiturate}
\]

The sodium salt occurs as a white, slightly bitter powder which is freely soluble in water and alcohol but practically insoluble in benzene and ether.

CLINICAL PHARMACOLOGY

Barbiturates are capable of producing all levels of CNS depression from excitation to complete sedation. Barbiturates can produce death. In high enough therapeutic doses, barbiturates induce anesthesia.

The barbiturates depress the central nervous system, decrease motor activity, alter cardiac function, and produce drowsiness, sedation, and hypnosis.

Barbiturate-induced sleep differs from physiological sleep. Sleep lab studies have demonstrated that barbiturates reduce the amount of time spent in the rapid eye movement (REM) phase of sleep or dreaming sleep. Also, Stages IV and V sleep are increased. Following abrupt cessation of barbiturates used regularly, patients may experience markedly increased dreaming, nightmares, and/or insomnia. Therefore, withdrawal of a single therapeutic dose may not be tolerated by the patient.

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The symptoms of barbiturate withdrawal can be severe and may cause death. More violent symptoms may include shock, hypothermia, convulsions, acute renal failure, cardiac arrest, delirium, and seizures. These symptoms usually appear in the following order: anxiety, muscle twitching, tachycardia, rapid eye movement, tremors, nausea, vomiting, oropharyngeal, and respiratory depression. Major withdrawal symptoms (tachycardia, tremors, and restlessness) may occur within hours and may last up to 2 weeks. The toxicity of these drugs is determined by the type and severity of the symptoms that occur. The signs may progress from minimal to severe and may last for a period of weeks. In some cases, the signs may persist for months. The signs of withdrawal may include: irritability, insomnia, and somatic complaints.

Symptoms of chronic intoxication include confusion, poor judgment, irritability, insomnia, and somatic complaints.

The average daily dose for the barbiturate addict is usually about 1.5 grams. Daily administration in excess of 400 milligrams (mg) of pentobarbital or secobarbital for several weeks to months may produce physical dependence and a risk of seizures. The maximum daily dose usually should not exceed 600 mg. The total daily dose of pentobarbital that the patient has been taking. The total daily amount of pentobarbital administered is 5 to 10 mg/kg, not to exceed 60 mg/kg. The usual adult dosage of pentobarbital sodium is 150 to 200 mg as a single IM injection; 250 mg to 400 mg daily may be used when prolonged sedation is desired. The total daily dose is decreased by 30 mg a day as long as withdrawal is proceeding smoothly. A modification of this regimen involves initiating treatment at the therapeutic dose levels. The characteristics of drug dependence to barbiturates include:

- Sensitivity to therapeutic doses.
- Abrupt withdrawal of barbiturates can produce severe symptoms and complications.
- Barbiturates can cause significant and prolonged changes in neurotransmitter function that can persist long after discontinuation of the drug.
- Barbiturates can cause a decrease in the activity of other neurotransmitter systems, which can lead to a variety of adverse effects.
- Barbiturates can cause changes in the function of the immune system, which can lead to an increased risk of infections.
- Barbiturates can cause changes in the function of the endocrine system, which can lead to a variety of adverse effects.
- Barbiturates can cause changes in the function of the nervous system, which can lead to a variety of adverse effects.
- Barbiturates can cause changes in the function of the cardiovascular system, which can lead to a variety of adverse effects.
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Section 1 - Identification

(a) **Product Identifier:** Pentobarbital Sodium Injection, USP

(b) **Product Code:** 25021-676

   **Common/Trade Name:** Nembutal® Sodium Solution

   **Chemical Name:** 5-ethyl-5-(1-methylbutyl) barbituric acid, sodium salt

   **Chemical Family:** Barbiturate

(c) **Product Use:** Pharmaceutical

   **Product Type:** Regulated Prescription Drug

   **Container Information:** Vials

(d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600

(e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

(a) **Classification:** Flammable liquids – Not Flammable

   Acute toxicity, Oral - Not Available

   Acute toxicity, Inhalation - Not Available

   Acute toxicity, Dermal - Not Available

   Reproductive toxicity - Not Available

   Specific target organ toxicity - - Not Available

(b) **Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):** - Not Available

c) **Description of Hazards:** - Not Available

(d) **Unknown Acute Toxicity:** - Not Available
Section 3 – Composition / Information on Ingredients

<table>
<thead>
<tr>
<th>(a) Chemical Name</th>
<th>(b) Common Name / Synonym</th>
<th>% Composition or other measure</th>
<th>(c) CAS No.</th>
<th>(d) Impurities / Stabilizing Additives</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-ethyl-5-(1-methylbutyl) barbituric acid, sodium salt</td>
<td>Pentobarbital Sodium</td>
<td>5</td>
<td>57-33-0</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Ethanol</td>
<td>10</td>
<td>64-17-5</td>
<td>N/A</td>
</tr>
<tr>
<td>1,2-propanediol</td>
<td>Propylene Glycol</td>
<td>40</td>
<td>57-55-6</td>
<td>N/A</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>Water for Injection</td>
<td>45</td>
<td>7732-18-5</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Section 4 - First Aid Measures

**Eye Exposure:** If product contacts the eyes rinse eyes thoroughly. Minimum flushing is for 15 minutes. If the exposure has resulted in an adverse effect, seek medical attention.

**Skin Exposure:** Basic hygiene should prevent any problems. If contact with the skin causes irritation, rinse with soap and running water. Remove contaminated clothing, taking care not to contaminate eyes. If an adverse reaction occurs, seek medical attention.

**Ingestion:** If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Maintain an open airway and obtain immediate medical attention.

**Injection:** See patient package insert in shipping carton for complete information.

**Inhalation:** In unlikely event that inhalation occurs and adverse effect occurs, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

**Notes to Physician:** See patient package insert in shipping carton for complete information.
Section 5 – Fire-fighting Measures

(a) **Extinguishing Media**

Use extinguishing media appropriate for surrounding fire; Water Spray, Carbon Dioxide, Dry Chemical, Halon, Foam, or any other "ABC" Class extinguisher.

(b) **Hazardous Combustion Products:**

Products of thermal decomposition may include irritating fumes and toxic gases.

(c) **Special Protective Equipment / Precautions:**

When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sodium oxides). If involved in a fire, evaporation of the water in this solution may make this product become combustible.

Section 6 - Accidental Release Measures

**Spill:**

For small releases of this compound; wear double latex or butyl rubber gloves and safety glasses. Clean up solution with a damp sponge, polypad, or other appropriate material for small spills then place in a bag and hold for waste disposal. Avoid producing sprays or mists of this product during cleanup. In case of large spill, clear the affected area and protect people. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal.

**Release to Air:**

Trained personnel using pre-planned procedures should respond to large or uncontrolled releases. Proper protective equipment should be used, including double natural rubber, neoprene or nitrile gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator in the event of a large spill.

**Release to Water:**

Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage
General Handling:  As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should meet the following provisions:

- Work should be performed in a designated area for working with hazardous drugs or Controlled Substances;
- Containment devices, such as a Biological Safety Cabinet, Ventilated Enclosures should be used;
- Contaminated waste must be properly handled;
- Work areas must be regularly decontaminated.

Storage Conditions: Store at controlled room temperature 20°-25°C (68°-77°F). Follow instructions provided in packaging.

### Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital Sodium</td>
<td>OSHA</td>
<td>PEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TLV</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
<tr>
<td>Ethanol</td>
<td>OSHA</td>
<td>PEL</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TLV</td>
<td>1880 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>OSHA</td>
<td>PEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TLV</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>OSHA</td>
<td>PEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>NE</td>
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<tr>
<td></td>
<td></td>
<td>TLV</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
</tbody>
</table>
(b) Engineering Controls


(c) Individual Protection Measures

<table>
<thead>
<tr>
<th>Respiratory Protection:</th>
<th>A respirator is not required for routine use of this product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Protection:</td>
<td>Not needed during normal use. For situations in which excessive splashes or sprays may be generated, wear splash goggles.</td>
</tr>
<tr>
<td>Skin Protection:</td>
<td>For situations, in which prolonged skin contact is anticipated, double glove, using natural rubber, neoprene, or nitrite gloves.</td>
</tr>
<tr>
<td>Other Protective Equipment:</td>
<td>During patient administration, use of lightweight cotton gown or other medical attire is recommended.</td>
</tr>
<tr>
<td>Additional Exposure Precautions:</td>
<td>Not established</td>
</tr>
</tbody>
</table>

Section 9 - Physical and Chemical Properties

<table>
<thead>
<tr>
<th>(a) Appearance</th>
<th>Clear, Colorless Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) Odor</td>
<td>Not Established</td>
</tr>
<tr>
<td>(c) Odor Threshold</td>
<td>None</td>
</tr>
<tr>
<td>(d) pH</td>
<td>Approximately 9.5</td>
</tr>
<tr>
<td>(e) Melting Point:</td>
<td>Not Established</td>
</tr>
<tr>
<td>(f) Initial Boiling Point:</td>
<td>Not Established</td>
</tr>
<tr>
<td>(g) Flash Point</td>
<td>Not Established</td>
</tr>
<tr>
<td>(h) Evaporation Rate:</td>
<td>Not Established</td>
</tr>
<tr>
<td>(i) Flammability</td>
<td>Not Established</td>
</tr>
<tr>
<td>(j) Upper Lower Flammability or Explosion Limits</td>
<td>Not Established</td>
</tr>
<tr>
<td>(k) Vapor Pressure:</td>
<td>Not Established</td>
</tr>
<tr>
<td>(l) Vapor Density:</td>
<td>Not Established</td>
</tr>
</tbody>
</table>
### Section 10 - Stability and Reactivity

<table>
<thead>
<tr>
<th>(a)</th>
<th>Reactivity</th>
<th>Flammable in the presence of a source of ignition when the temperature is above the flash point.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>Chemical Stability</td>
<td>This product is stable when properly stored per label instructions.</td>
</tr>
<tr>
<td>(c)</td>
<td>Possibility of Hazardous Reactions</td>
<td>If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, and sodium oxides).</td>
</tr>
<tr>
<td>(d)</td>
<td>Conditions to Avoid</td>
<td>Avoid heat, light, and contact with incompatible chemicals</td>
</tr>
<tr>
<td>(e)</td>
<td>Incompatible Materials</td>
<td>This product is generally compatible with common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.</td>
</tr>
<tr>
<td>(f)</td>
<td>Hazardous Decomposition Products</td>
<td>Hazardous decomposition products formed under fire conditions. - Carbon oxides</td>
</tr>
</tbody>
</table>

### Section 11 - Toxicological Information

<table>
<thead>
<tr>
<th>(a)</th>
<th>Likely Routes of Exposure</th>
<th>Eyes and skin contact, inhalation, and ingestion.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>Symptoms related to the physical, chemical and toxicological characteristics</td>
<td>This product is a Controlled Substance. The chief health hazard associated with overexposures during normal occupational use and handling is irritation of contaminated</td>
</tr>
</tbody>
</table>
(c) Delayed and immediate effects and also chronic effects from short and long term exposure

Respiratory disorder, gastrointestinal disturbance, dizziness, ataxia, and headache.

d) Acute Toxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pentobarbital Sodium</td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Rat</td>
<td>118 mg/kg</td>
</tr>
<tr>
<td>Pentobarbital Sodium</td>
<td>LD₅₀</td>
<td>Oral</td>
<td>Mouse</td>
<td>239 mg/kg</td>
</tr>
<tr>
<td>Pentobarbital Sodium</td>
<td>TD₉₀</td>
<td>Oral</td>
<td>Woman</td>
<td>60 mg/kg</td>
</tr>
</tbody>
</table>

(e) Hazardous Chemical Listings

NTP: No   IARC: No   OSHA: No

Section 12 - Ecological Information

(a) Ecotoxicity

No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

(b) Persistence and degradability

The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

(c) Bioaccumulative potential

The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

(d) Mobility in soil

Not available

(e) Other Adverse Effects

Not available
Section 13 - Disposal Considerations

Dispose of as a Controlled Substance in accordance with appropriate U.S. Federal, State, and local regulations.

Section 14 - Transport Information

<table>
<thead>
<tr>
<th>(a)</th>
<th>UN Number</th>
<th>Not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b)</td>
<td>UN Proper Shipping Name</td>
<td>Not available</td>
</tr>
<tr>
<td>(c)</td>
<td>Transport Hazard Class(es)</td>
<td>Not available</td>
</tr>
<tr>
<td>(d)</td>
<td>Packing Group</td>
<td>Not available</td>
</tr>
<tr>
<td>(e)</td>
<td>Environmental Hazards</td>
<td>Not available</td>
</tr>
<tr>
<td>(f)</td>
<td>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</td>
<td>Not available</td>
</tr>
<tr>
<td>(g)</td>
<td>Special Precautions</td>
<td>Not available</td>
</tr>
</tbody>
</table>

DOT: Not regulated
ICAO/IATA: Not available
IMO: Not available

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:
TSCA - No
CERCLA - Not on this list
SARA 302, 304, 313 - Not on this list
OSHA - Target Organ Effect, Toxic by ingestion, Reproductive Hazard.

OTHER U.S. FEDERAL REGULATIONS: This product is regulated under the DEA and FDA per Schedules of Controlled Substances, by section 202 of the Controlled Substances Act (21 U.S.C. 812). Pentobarbital Sodium is a Schedule II material; DEA Code #2270. Drug Class: Depressants.

Section 16 - Other Information
As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>American Conference of Governmental Industrial Hygienists</td>
</tr>
<tr>
<td>AIHA</td>
<td>American Industrial Hygiene Association</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>CAS Number</td>
<td>Chemical Abstract Service Registry Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>Comprehensive Environmental Response Compensation and Liability Act (of 1980)</td>
</tr>
<tr>
<td>CHAN</td>
<td>Chemical Hazard Alert Notice</td>
</tr>
<tr>
<td>CHEMTREC</td>
<td>Chemical Transportation Emergency Center</td>
</tr>
<tr>
<td>DOT</td>
<td>Department of Transportation</td>
</tr>
<tr>
<td>DSL</td>
<td>Domestic Substances List</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System of Classification and Labelling of Chemicals</td>
</tr>
<tr>
<td>HEPA</td>
<td>High Efficiency Particulate Air (Filter)</td>
</tr>
<tr>
<td>HMIS</td>
<td>Hazardous Materials Identification System</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>ICAO/IATA</td>
<td>International Civil Aviation Organization/International Air Transport Association</td>
</tr>
<tr>
<td>IMO</td>
<td>International Maritime Organization</td>
</tr>
<tr>
<td>KOW</td>
<td>Octanol/Water Partition Coefficient</td>
</tr>
<tr>
<td>LEL</td>
<td>Lower Explosive Limit</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet</td>
</tr>
<tr>
<td>MSHA</td>
<td>Mine Safety and Health Administration</td>
</tr>
<tr>
<td>NA</td>
<td>Not Applicable, except in Section 14 where NA = North America</td>
</tr>
<tr>
<td>NE</td>
<td>Not Established</td>
</tr>
<tr>
<td>NADA</td>
<td>New Animal Drug Application</td>
</tr>
<tr>
<td>NAIF</td>
<td>No Applicable Information Found</td>
</tr>
<tr>
<td>NCI</td>
<td>National Cancer Institute</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>NDSL</td>
<td>Non-Domestic Substances List</td>
</tr>
<tr>
<td>NFPA</td>
<td>National Fire Protection Association</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>NOS</td>
<td>Not Otherwise Specified</td>
</tr>
<tr>
<td>NTP</td>
<td>National Toxicology Program</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>OEL</td>
<td>Occupational Exposure Limit</td>
</tr>
<tr>
<td>PEL</td>
<td>Permissible Exposure Limit (OSHA)</td>
</tr>
<tr>
<td>RCRA</td>
<td>Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RQ</td>
<td>Reportable Quantity</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>STEL</td>
<td>Short Term Exposure Limit</td>
</tr>
<tr>
<td>TLV</td>
<td>Threshold Limit Value (ACGIH)</td>
</tr>
<tr>
<td>TPQ</td>
<td>Threshold Planning Quantity</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substances Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>Time Weighted Average/8 Hours Unless Otherwise Noted</td>
</tr>
<tr>
<td>UEL</td>
<td>Upper Explosive Limit</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
</tr>
<tr>
<td>WEEL</td>
<td>Workplace Environmental Exposure Level (AIHA)</td>
</tr>
<tr>
<td>NDC #</td>
<td>Amount per Volume</td>
</tr>
<tr>
<td>-------</td>
<td>------------------</td>
</tr>
<tr>
<td>25021-676-20</td>
<td>1,000 mg per 20 mL</td>
</tr>
<tr>
<td>25021-676-50</td>
<td>2,500 mg per 50 mL</td>
</tr>
</tbody>
</table>
Sagent Pharmaceuticals, Inc.
Wholesaler / Distributor
Return Goods Policy

Prior Authorization:

Prior authorization from Sagent Pharmaceuticals, or Sagent, in the form of a Returned Goods Authorization (RGA), is required for all product returns. Prior authorization and issuance of credit is subject to the below terms and conditions. Sagent’s only authorized return facility is located at 4580 Mendenhall Road, Memphis, TN 38141 (“Sagent Memphis”). Sagent is not responsible for product shipping cost or other charges for products returned to a facility other than Sagent Memphis.

Please contact Sagent customer service department at 866-625-1618 for RGA assistance.

Return Shipment Instructions:

Returned products must contain a packing list with customer account information and debit memo (RGA) number clearly designated. Use only one debit memo (RGA) number per return shipment. If a return shipment is multiple boxes, photocopy paperwork with debit memo (RGA) number and place in each box. It is suggested that the return be insured and records kept. Sagent is not responsible for return shipments prior to receipt by Sagent Memphis.

All pre-authorized returns, evidenced by an RGA, must be sent to the following address:

Sagent Pharmaceuticals
4580 Mendenhall Road
Memphis, TN 38141

Returnable Items:

- Product must be within six (6) months prior to and twelve (12) months post expiration.
- Product must have a VALID Sagent lot number and expiry date.
- Product must be in original, unaltered container/trade package.

Conditions for Returned Goods Credit:

- A valid Return Goods Authorization (RGA) Number must accompany all returns for proper credit.
- RGA Numbers are valid for 90 days from issuance. Expired RGA Numbers will be considered invalid and no credit will be issued.

Revised on 10/17/07
• All returned product must be received at Sagent Memphis within 90 days of RGA issuance to receive credit. Products that have been destroyed by customers or agent of customer will not receive credit.
• Partial will not be accepted.
• Product must not be damaged by fire, smoke, heat, water, acts of God or be returned as the result of bankruptcy proceedings.
• Product must not be damaged by improper handling, storage or shipping.
• Product must not require refrigeration.
• Packages must not be marked or disfigured in any way.
• Reimbursement price will be based on the lower of the customer’s original purchase price or current price.
• Sagent will issue an eighty-percent (80%) credit allowance based on the lower of the customer’s original purchase price or current price.
• Credit will be allowed toward future purchases of any Sagent products. Credits from returned goods are valid for one (1) year from the date of issuance.
• Returns totaling fifty dollars ($50.00) or less are not eligible for credit.
• Product must be returned by the customer who purchased the product from Sagent. Credit will be issued to customer’s account.
• Returned products will be verified by Sagent and the final credit will be calculated based upon Sagent’s count.

Shipping Errors/Damaged Shipments:

Products shipped in error by Sagent are subject to 100% replacement credit if reported to Sagent within ten (10) days of receipt and returned to Sagent in original condition within 25 days of receipt. Products damaged in transit are subject to 100% replacement credit if reported to Sagent within ten (10) working days of receipt and returned to Sagent within 25 days of receipt. Contact Sagent Customer Service at 866-625-1618 to report shipping errors or damaged shipments.

Return Transportation Charges:

Prepaid by customer except when return is due to shipping error or products damaged in transit.

Terms of Return Policy:

• Product(s) returned to the wholesaler/distributor by their customer(s) are not returnable to Sagent.
• Sagent will not reimburse customer costs relating to third-party returns, destruction charges, shipping costs or processing.
• All returns are subject to review by Sagent. Issuance of RGA does not guarantee credit. Credit issuance is dependent on confirmed receipt/review of return goods.
• Returns made to Sagent or its agent without prior approval, as evidenced by a Sagent RGA, will be destroyed and credit will not be issued.
• Sagent may, at its discretion, make exceptions to the returned goods policy based upon extenuating circumstances.

Revised on 10/17/07
Non-Returnable Items/no credit:

- Non-authorized products.
- Products with more than six (6) months dating.
- Opened products or products not in original containers/packaging.
- Product purchased as close-outs or other special pricing, e.g., free goods or short-dated promotions.
- Shipments received with concealed damages not reported within 10 days of receiving the shipment.
- Items not properly stored as outlined by the Prescription Drug Marketing Act.
- Private label, repackaged products or products not in the original Sagent container.
- Products discontinued for more than 12 months.
- Product for which proof of purchase cannot be verified.
- Products returned outside of this policy will not receive credit.

Product Recall:

Should a product recall or withdrawal be necessary, Sagent will compensate its customers only for the reasonable expense incurred in performing all recall services requested by Sagent.

Other:

Sagent Pharmaceutical reserves the right to impose a handling fee on all returned goods. Federal law prohibits our representatives from transporting products between accounts or picking-up returns. Sagent reserves the right to inspect all authorized returns prior to issuing credit and to destroy products deemed unfit for sale.