For Immediate Release

February 27, 2019

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Aminocaproic Acid Injection, USP is supplied as a 20 mL Multiple Dose Vial in a shelf pack of 25. The strength is 250 mg/mL

American Regent Announces the Re-Introduction of Aminocaproic Acid Injection, USP; AP Rated and Therapeutically Equivalent to Amicar®*[1]

Shirley, NY - American Regent today announced the re-introduction of Aminocaproic Acid Injection, USP, a therapeutically equivalent generic alternative to Amicar®.[1,2]

Aminocaproic Acid Injection, USP is useful in enhancing hemostasis when fibrinolysis contributes to bleeding, "With the re-introduction of Aminocaproic Acid Injection, USP, we continue to demonstrate our commitment to ensuring both patients and providers have access to treatment options that may not be readily available due to drug shortages," said Ken Keller, *President and CEO* of American Regent, Inc.

In life-threatening situations, fresh whole blood transfusions, fibrinogen infusions, and other emergency measures may be required. Aminocaproic acid should not be used when there is evidence of an active intravascular clotting process.

Product is available for immediate shipment. Customers can order Aminocaproic Acid Injection, USP through their wholesaler/distributor or by contacting our Customer Support Group at 1-800-645-1706.

Aminocaproic Acid Injection, USP is supplied as follows:

PACK NDC#	Strength	Supplied As	Shelf Pack
0517-9120-25	250 mg/mL	20 mL Multiple Dose Vial	25

*Amicar® is a registered trademark of Clover Pharmaceuticals Corp.

See the following Important Safety Information and accompanying Full Prescribing Information.

For additional information, please visit americanregent.com.

References: 1. Aminocaproic Acid Injection, USP [package insert]. Shirley, NY: American Regent, Inc.; 2018. 2. Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=071192, Accessed September 27, 2018.

PP-AO-US-0003 1/2019

AMINOCAPROIC ACID INJECTION, USP

For intravenous infusion after dilution.

INDICATIONS AND USAGE
Aminocaproic Acid Injection is useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, fresh whole blood transfusions, fibrinogen infusions, and other emergency measures may be required.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Aminocaproic acid should not be used when there is evidence of an active intravascular clotting process.

WARNINGS
Aminocaproic Acid Injection, USP contains benzyl alcohol as a preservative. The administration of medications containing benzyl alcohol as a preservative to premature neonates has been associated with a fatal "Gasping Syndrome."

Aminocaproic acid should not be used in hematuria of upper urinary tract origin, unless the possible benefits outweigh the risk.

Skeletal muscle weakness with necrosis of muscle fibers has been reported following prolonged administration. The possibility of cardiac muscle damage should be considered when skeletal myopathy occurs. One case of cardiac and hepatic lesions observed in man has been reported. The patient received 2 g of aminocaproic acid every 6 hours for a total dose of 26 g. Death was due to continued cerebrovascular hemorrhage.

PRECAUTIONS
General: Aminocaproic acid inhibits both the action of plasminogen activators and to a lesser degree, plasmin activity. The drug should NOT be administered without a definite diagnosis and/or laboratory finding indicative of hyperfibrinolysis (hyperplasminemia).

Rapid intravenous administration of the drug should be avoided since this may induce hypotension, bradycardia, and/or arrhythmia.

Thrombophlebitis, a possibility with all intravenous therapy, should be guarded against by strict attention to the proper insertion of the needle and the fixing of its position.

Epsilon-aminocaproic acid should not be administered with Factor IX Complex concentrates or Anti-Inhibitor Coagulant concentrates, as the risk of thrombosis may be increased.

Laboratory Tests: The use of aminocaproic acid should be accompanied by tests designed to determine the amount of fibrinolysis present.

Drug/Laboratory Test Interactions: Prolongation of the template bleeding time has been reported during continuous intravenous infusion of aminocaproic acid at dosages exceeding 24 g/day. Higher plasma concentrations of aminocaproic acid may occur in patients with severe renal failure.

Pregnancy: Pregnancy Category C. Aminocaproic acid should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when aminocaproic acid is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. Aminocaproic Acid Injection, USP contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with a fatal "gasping syndrome" in neonates.

ADVERSE REACTIONS
The following adverse experiences have been reported:
General: Edema, headache, malaise.
Hypersensitivity Reactions: Allergic and anaphylactoid reactions, anaphylaxis.
Local Reactions: Injection site reactions, pain and necrosis.
Cardiovascular: Bradycardia, hypotension, peripheral ischemia, thrombosis.
Gastrointestinal: Abdominal pain, diarrhea, nausea, vomiting.
Hematologic: Agranulocytosis, coagulation disorder, leukopenia, thrombocytopenia.
Musculoskeletal: CPK increased, muscle weakness, myalgia, myopathy, myositis, rhabdomyolysis.
Neurologic: Confusion, convulsions, delirium, dizziness, hallucinations, intracranial hypertension, stroke, syncope.
Respiratory: Dyspnea, nasal congestion, pulmonary embolism.
Skin: Pruritus, rash.
Special Senses: Tinnitus, vision decreased, watery eyes.
Urogenital: BUN increased, renal failure. There have been some reports of dry ejaculation during the period of aminocaproic acid treatment reported to date in hemophilia patients.

OVERDOSAGE
Effects have ranged from no reaction to transient hypotension to severe acute renal failure leading to death. One patient with a history of brain tumor and seizures experienced seizures after receiving an 8 gram bolus injection of aminocaproic acid. Aminocaproic acid is removed by hemodialysis and may be removed by peritoneal dialysis.

DOSAGE AND ADMINISTRATION
RAPID INJECTION OF AMINOCAPROIC ACID INJECTION, USP UNDILUTED INTO A VEIN IS NOT RECOMMENDED.

For additional Safety Information, please see Full Prescribing Information.

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:
Email: pv@americanregent.com; Fax: 1-610-650-0170;
Phone: 1-800-734-9236

ADEs may also be reported to the FDA at 1-800-FDA-1088 or to
www.fda.gov/Medwatch

Drug Information:
1-888-354-4855
(9:00 am - 5:00 pm Eastern Time, Monday - Friday)

For urgent drug information outside of normal business hours, assistance is available at:
1-877-845-6371

About American Regent
American Regent, Inc. is a Daiichi Sankyo Group company with sales approaching $1B. American Regent develops, manufactures and supplies high-quality sterile injectables for healthcare providers and their patients.

Supporting patient health is the guiding principle of American Regent and their promise is to provide the healthcare marketplace with a steady supply and broad portfolio of branded and generic specialty injectables. American Regent is a top-10 injectable supplier in therapeutic areas including IV additives, anti-inflammatories, diuretics, cytotoxics and diagnostic dyes. Additionally, for nearly 20 years, American Regent has been a leader in IV iron therapy and supplies two of the top-selling brands in the U.S. today.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo
Daiichi Sankyo is a global pharmaceutical company with corporate origins in Japan. We provide innovative products and services in more than 20 countries around the world. With more than 100 years of scientific expertise, our company draws upon a rich legacy of innovation and a robust pipeline of promising new medicines to help patients.

Through the outstanding knowledge and commitment of our 15,000 employees worldwide, we create innovative new and generic medicines, and new methods of drug discovery and delivery. We share a passion for innovation, as well as compassion for the patients around the world who are in need of our medicines.

For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.