Aminocaproic Acid Tablets, USP 500mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Aminocaproic acid tablets, USP is useful in enhancing hemostasis when fibrinolysis contributes to bleeding. In life-threatening situations, transfusion of appropriate blood products and other emergency measures may be required. Take Aminocaproic Acid Tablets exactly as your doctor tells you to take it.
2	Dosage	What is the recommended dosage?	For the treatment of acute bleeding syndromes due to elevated fibrinolytic activity, it is suggested that 5 aminocaproic acid tablets 1000 mg Tablets or 10 aminocaproic acid tablets 500 mg Tablets (5 g) be administered during the first hour of treatment, followed by a continuing rate of 1 aminocaproic acid tablets 1000 mg Tablet or 2 aminocaproic acid tablets 500 mg Tablets (1 g) per hour. This method of treatment would ordinarily be continued for about 8 hours or until the bleeding situation has been controlled.
3	Administration	How do I take it?	Take Aminocaproic Acid Tablets exactly as your doctor tells you to take it.
4	Formulation	Can tablet be crushed?	Take Aminocaproic Acid Tablets exactly as your doctor tells you to take it.
5	Administration	What do I do if I miss a dose?	If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take 2 doses at the same time. Please contact your physician for further queries.
6	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric patients have not been established.
8	Mechanism	Mechanism of Action	Aminocaproic acid inhibits both the action of plasminogen activators and to a lesser degree, plasmin activity.
9	Warning	Black Box Warning	None
10	Lactation	Use in Lactation	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.
11	Pregnancy	Use in Pregnancy	Aminocaproic Acid Tablets are categorised Pregnancy Category C: Animal reproduction studies have not been conducted with aminocaproic acid. It is also not known whether aminocaproic acid can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Aminocaproic acid should be given to a pregnant woman only if clearly needed.

12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	None
14	Side effects	What are the common side effects?	Aminocaproic acid is generally well tolerated. The following adverse reactions were reported with Aminocaproic acid: edema, headache, malaise, allergic and anaphylactoid reactions, anaphylaxis, bradycardia, hypotension, peripheral ischemia, thrombosis, abdominal pain, diarrhea, nausea, vomiting, agranulocytosis, coagulation disorder, leukopenia, thrombocytopenia, CPK increased, muscle weakness, myalgia, myopathy, myositis, rhabdomyolysis, confusion, convulsions, delirium, dizziness, hallucinations, intracranial hypertension, stroke, syncope, dyspnea, nasal congestion, pulmonary embolism, pruritis, rash, tinnitus, vision decreased and watery eyes.
15	Storage	What are the storage conditions?	Store at 20° to 25°C (68° to 77°F); Dispense in Tight Containers; Do Not Freeze.
16	Dispensing	How to Dispense?	Dispense in Tight Containers.
17	Contraindication	What are the contraindications of (medication).	Aminocaproic acid should not be used when there is evidence of an active intravascular clotting process. When there is uncertainty as to whether the cause of bleeding is primary fibrinolysis or disseminated intravascular coagulation (DIC), this distinction must be made before administering aminocaproic acid. The following tests can be applied to differentiate the two conditions: • Platelet count is usually decreased in DIC but normal in primary fibrinolysis. • Protamine Para coagulation test is positive in DIC; a precipitate form when protamine sulfate is dropped into citrated plasma. The test is negative in the presence of primary fibrinolysis. • The euglobulin clot lysis test is abnormal in primary fibrinolysis but normal in DIC. Aminocaproic acid must not be used in the presence of DIC without concomitant heparin.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it supplied?	Each white to off white colored, round shaped, uncoated tablets with break line debossed with "MA" and "17" on one side and plain on other side, contains 500 mg of aminocaproic acid. Bottle of 30 – NDC 72205-049-30
19	Ingredients	Active and Inactive Ingredients	**Active**: Aminocaproic acid **Inactive**: colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, povidone and stearic acid.
20	Coating	What is the type of coating?	Uncoated tablets
Allergens			

21	Ingredients	Is it Vegetarian?	Yes, Free from Animal Products/Derivatives.
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
35	Ingredients	Does it contain povidone?	Yes, Inactive ingredients included povidone.
36	Ingredients	Does it contain Iodine?	Yes, Inactive ingredients included crospovidone, which is povidone-iodine complex.
37	Ingredients	Does it contain latex?	No
38	Ingredients	Does it contain alcohol?	Yes, Aminocaproic acid API contains Iso-propyl alcohol NMT 2000 PPM
39	Ingredients	Does it contain dyes?	No
40	Ingredients	Does it contain flavor?	No
41	Ingredients	Does it contain Lactose?	No
42	Ingredients	Does it contain Nuts?	No
43	Ingredients	Does it contain Preservatives?	No
44	Ingredients	Does it contain Soy products?	No
45	Ingredients	Does it contain peanut?	No
46	Ingredients	Does it contain nickel?	No
Miscellaneous			
47	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products

48	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
49	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company.
50	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
51	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.
52	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 Issued on: 02/2020