Alphanate®
antihemophilic factor/von Willebrand factor complex (human)

ALPHANATE offers convenient dosing for patients with hemophilia A

Hemorrhagic event	Dosage (IU FVIII:C/kg body weight)
Minor hemorrhage Large bruises, significant cuts or scrapes, uncomplicated joint hemorrhage	**Bring FVIII:C to 30% (15 IU FVIII/kg BID)** until hemorrhage stops and healing is achieved (1 to 2 days)
Moderate hemorrhage Nose, mouth, and gum bleeds; dental extractions; hematuria	**Bring FVIII:C to 50% (25 IU FVIII/kg BID)** until healing is achieved (2 to 7 days on average)
Major hemorrhage Joint hemorrhage, muscle hemorrhage, major trauma, hematuria, intracranial and intraperitoneal bleeding	**Bring FVIII:C to 80% to 100% for at least 3 to 5 days (40 to 50 IU FVIII/kg BID).** Maintain at 50% (25 IU FVIII/kg BID) until healing is achieved. Major bleeds may require treatment for up to 10 days. Intracranial bleeds up to 6 months
Surgery	**Prior to surgery, bring level of FVIII:C to 80% to 100% (40 to 50 IU FVIII/kg).** Maintain at 60% to 100% (30 to 50 IU FVIII/kg BID) for the next 7 to 10 days or until healing is achieved

Dosing requirements and frequency of dosing are calculated on the basis of an expected initial response of 2% FVIII:C increase per IU FVIII:C/kg body weight (ie, 2% per IU/kg) and an average half-life for FVIII:C of 17.9 hours. If dosing studies have determined that a particular patient exhibits a lower-than-expected response and the medication has a shorter half-life, the dose and the frequency of dosing should be adjusted accordingly.

Plasma FVIII levels should be monitored periodically to evaluate individual patient response to the dosage regimen. Depending on the level of the inhibitor and/or clinical response, it may be appropriate to use an alternative "bypass" therapeutic agent.

FVIII=factor VIII

Please see Important Safety Information on page 2 and see full Prescribing Information available at www.alphanate.com/HCP.

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Indications

ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for:

- Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with factor VIII (FVIII) deficiency due to hemophilia A
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (type 3) undergoing major surgery

Important Safety Information

ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

Anaphylaxis and severe hypersensitivity reactions are possible with ALPHANATE. Discontinue use of ALPHANATE if hypersensitivity symptoms occur, and initiate appropriate treatment.

Development of procoagulant activity-neutralizing antibodies (inhibitors) has been detected in patients receiving FVIII-containing products. Carefully monitor patients treated with AHF products for the development of FVIII inhibitors by appropriate clinical observations and laboratory tests.

Thromboembolic events have been reported with AHF/VWF complex (human) in VWD patients, especially in the setting of known risk factors.

Intravascular hemolysis may occur with infusion of large doses of AHF/VWF complex (human).

Rapid administration of a FVIII concentrate may result in vasomotor reactions.

Because ALPHANATE is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

Monitor for development of FVIII and VWF inhibitors. Perform appropriate assays to determine if FVIII and/or VWF inhibitor(s) are present if bleeding is not controlled with expected dose of ALPHANATE.

The most frequent adverse drug reactions reported with ALPHANATE in >1% of infusions were pruritus, headache, back pain, paresthesia, respiratory distress, facial edema, pain, rash, and chills.

Please see full Prescribing Information available at www.alphanate.com/HCP.

Reference: ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) Prescribing Information. Grifols.

GRIFOLS

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