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

ALPHANATE offers convenient dosing for patients with VWD undergoing surgical or invasive procedures

Minor surgery/bleeding

	VWF:RCo	Target FVIII:FC activity levels
Preoperative/preprocedure dose	**Adults:** 60 IU VWF:RCo/kg body weight **Pediatrics:** 75 IU VWF:RCo/kg body weight	40 to 50 IU/dL
Maintenance dose	**Adults:** 40 to 60 IU VWF:RCo/kg body weight at 8- to 12-hour intervals as clinically needed for 1 to 3 days **Pediatrics:** 50 to 75 IU VWF:RCo/kg body weight at 8- to 12-hour intervals as clinically needed for 1 to 3 days	40 to 50 IU/dL
Safety monitoring	Peak and trough at least once daily	Peak and trough at least once daily
Therapeutic goal (trough)*	>50 IU/dL	>50 IU/dL
Safety parameter†	Should not exceed 150 IU/dL	Should not exceed 150 IU/dL

Major surgery/bleeding (except type 3 patients undergoing major surgery)

	VWF:RCo	Target FVIII:FC activity levels
Preoperative/preprocedure dose	**Adults:** 60 IU VWF:RCo/kg body weight **Pediatrics:** 75 IU VWF:RCo/kg body weight	100 IU/dL
Maintenance dose	**Adults:** 40 to 60 IU VWF:RCo/kg body weight at 8- to 12-hour intervals as clinically needed for at least 3 to 7 days **Pediatrics:** 50 to 75 IU VWF:RCo/kg body weight at 8- to 12-hour intervals as clinically needed for at least 3 to 7 days	100 IU/dL
Safety monitoring	Peak and trough at least once daily	Peak and trough at least once daily
Therapeutic goal (trough)*	>50 IU/dL	>50 IU/dL
Safety parameter†	Should not exceed 150 IU/dL	Should not exceed 150 IU/dL

* The therapeutic goal is referenced in the NHLBI Guidelines: Nichols WL et al. HHS, NIH, NHLBI 2007: NIH No. 08-5832.
† The safety parameter is extracted from Mannucci PM et al. *Blood Transfus*. 2009;7(2):117-126.

FVIII, factor VIII; VWF, von Willebrand factor; VWD, von Willebrand disease.

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

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antihemophilic factor/von Willebrand factor complex (human)

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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