

Alphanate®

antihemophilic factor/von Willebrand factor complex (human)



Use this doctor discussion guide to prepare for the next appointment with your hematologist

General information

How long ago was your last appointment with your hematologist?

- 6 months
 - 1 year
 - Other _____
-

What is your prescribed treatment regimen?

- On-demand
- Prophylaxis

Are you happy with your current treatment regimen?

- Yes
- No

Why? _____

Inhibitor risk profile

Do you currently have an inhibitor?

- Yes
- No

If yes, what is the titer measurement? BU (Bethesda Units)

If yes, how is your inhibitor being managed?

Have you had a previous inhibitor?

- Yes
- No

If yes, how was it managed?

If yes, how long has it been since you tested negative for the inhibitor?

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Symptoms since your last appointment

How many bleeds have you experienced since your last appointment? _____

How does that compare with your previous experience?

- Less frequent
- Same
- More frequent

Do your breakthrough bleeds seem to occur at a predictable time, such as your last day of prophylaxis treatment?

- Yes
- No

If yes, please explain: _____

When treating breakthrough bleeds, how has your treatment changed since your last appointment?

- Less factor than usual
- Same
- More factor than usual

Do you have pain related to hemophilia?

- Yes
- No

If yes, where? _____

If you have pain related to your hemophilia A, how has it changed since your last appointment?

Pain frequency:

- Less frequent
- Same
- More frequent

Pain intensity:

- Less intense
- Same
- More intense

Have you experienced any joint swelling?

- Yes
- No

If yes, where? _____

Do you measure your problem joints?

- Yes
- No

If yes, current measurements: _____

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Quality of life

Are there aspects of your treatment that you would like to change?

- Yes
- No

If yes, what are they? _____

How could these changes positively impact your life? _____

Do you know of the various services available that may help you manage your hemophilia A?

Check all that apply:

- Educational offerings
- Factors for Health program
- Local chapter support
- Manufacturer-sponsored patient support programs
- Physical therapy
- Social worker support
- Support groups in your area

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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.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1.800.FDA.1088.

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