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Hemophilia and inhibitors

Alphanate®
Antihemophilic Factor/von Willebrand Factor Complex (Human)

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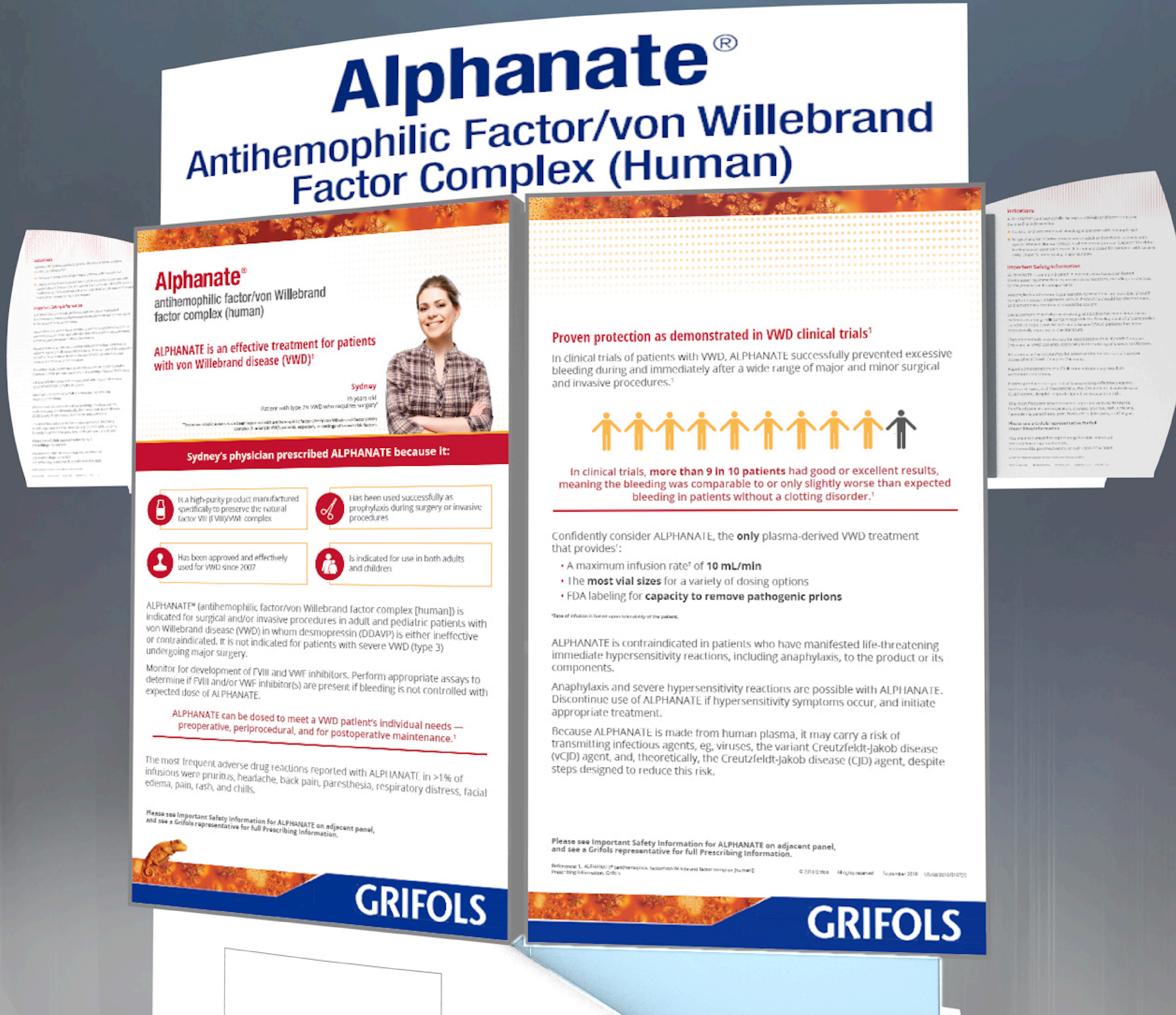
Alphanate®
Antihemophilic Factor/von Willebrand Factor Complex (Human)
Alphanate®
antihemophilic factor/von Willebrand factor complex (human)
ALPHANATE is an effective treatment for patients with von Willebrand disease (VWD)1
Sydney
Sydney's physician prescribed ALPHANATE because it:
Is a high-purity product manufactured specifically to preserve the natural factor VIII (FVIII)/VWF complex
Has been used successfully as prophylaxis during surgery or invasive procedures
Has been approved and effectively used for VWD since 2007
Is indicated for use in both adults and children
ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for 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.
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.
ALPHANATE can be dosed to meet a VWD patient's individual needs — preoperative, periprocedural, and for postoperative maintenance.1
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 Important Safety Information for ALPHANATE on adjacent panel, and see a Grifols representative for full Prescribing Information.
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Proven protection as demonstrated in VWD clinical trials1
In clinical trials of patients with VWD, ALPHANATE successfully prevented excessive bleeding during and immediately after a wide range of major and minor surgical and invasive procedures.1
In clinical trials, more than 9 in 10 patients had good or excellent results, meaning the bleeding was comparable to or only slightly worse than expected bleeding in patients without a clotting disorder.1
Confidently consider ALPHANATE, the only plasma-derived VWD treatment that provides1:
• A maximum infusion rate* of 10 mL/min
• The most vial sizes for a variety of dosing options
• FDA labeling for capacity to remove pathogenic prions
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.
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.
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Alphanate®

antihemophilic factor/von Willebrand factor complex (human)

ALPHANATE is an effective treatment for patients with von Willebrand disease (VWD)[1]

Sydney
35 years old
Patient with type 2N VWD who requires surgery*

*Thromboembolic events have been reported with antihemophilic factor (AHF)/von Willebrand factor (VWF) complex (human) in VWD patients, especially in settings of known risk factors.

Sydney's physician prescribed ALPHANATE because it:

- Is a high-purity product manufactured specifically to preserve the natural factor VIII (FVIII)/VWF complex
- Has been used successfully as prophylaxis during surgery or invasive procedures
- Has been approved and effectively used for VWD since 2007
- Is indicated for use in both adults and children

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

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.

ALPHANATE can be dosed to meet a VWD patient's individual needs — preoperative, periprocedural, and for postoperative maintenance.[1]

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Proven protection as demonstrated in VWD clinical trials[1]

In clinical trials of patients with VWD, ALPHANATE successfully prevented excessive bleeding during and immediately after a wide range of major and minor surgical and invasive procedures.[1]

In clinical trials, more than 9 in 10 patients had good or excellent results, meaning the bleeding was comparable to or only slightly worse than expected bleeding in patients without a clotting disorder.[1]

Confidently consider ALPHANATE, the **only** plasma-derived VWD treatment that provides[1]:

- A maximum infusion rate† of **10 mL/min**
- The **most vial sizes** for a variety of dosing options
- FDA labeling for **capacity to remove pathogenic prions**

†Rate of infusion is based upon tolerability of the patient.

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

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Reference: 1. ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) Prescribing Information. Grifols.

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.

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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.

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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.

Alphanate®

Antihemophilic Factor/von Willebrand Factor Complex (Human)

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

What you need, when you need it

Patient With Inhibitors | High-volume Patient | Previously Untreated Patient

ALPHANATE can be dosed to meet a patient's individual needs, based on[1]

- Severity of disease
- Severity of hemorrhage
- Presence of inhibitors
- Desired factor VIII levels

Monitor for the development of factor VIII (FVIII) and von Willebrand factor (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.

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Confidently consider ALPHANATE, a proven choice for all patient types

ALPHANATE **replaces exactly what is missing** from the coagulation cascade, with the added benefits of von Willebrand factor

$t_{½}$ With ALPHANATE, the mean in vivo half-life is 17.9 hours

0 CASES Since launch in 1997, there has **never been a confirmed case** of prion or virus transmission with ALPHANATE

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1. ALPHANATE® (antihemophilic factor/von Willebrand factor complex) [Human]. Prescribing Information. Grifols.

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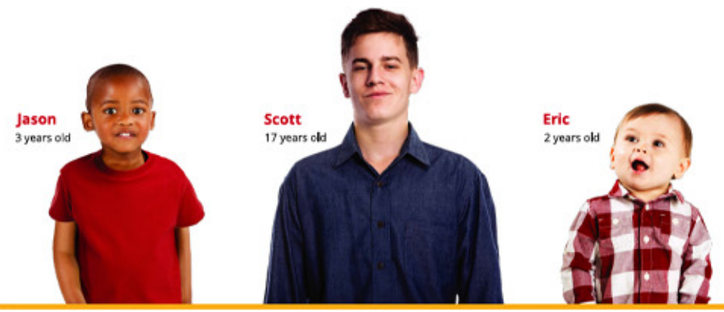
Alphanate®

antihemophilic factor/von Willebrand factor complex (human)

What you need, when you need it



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