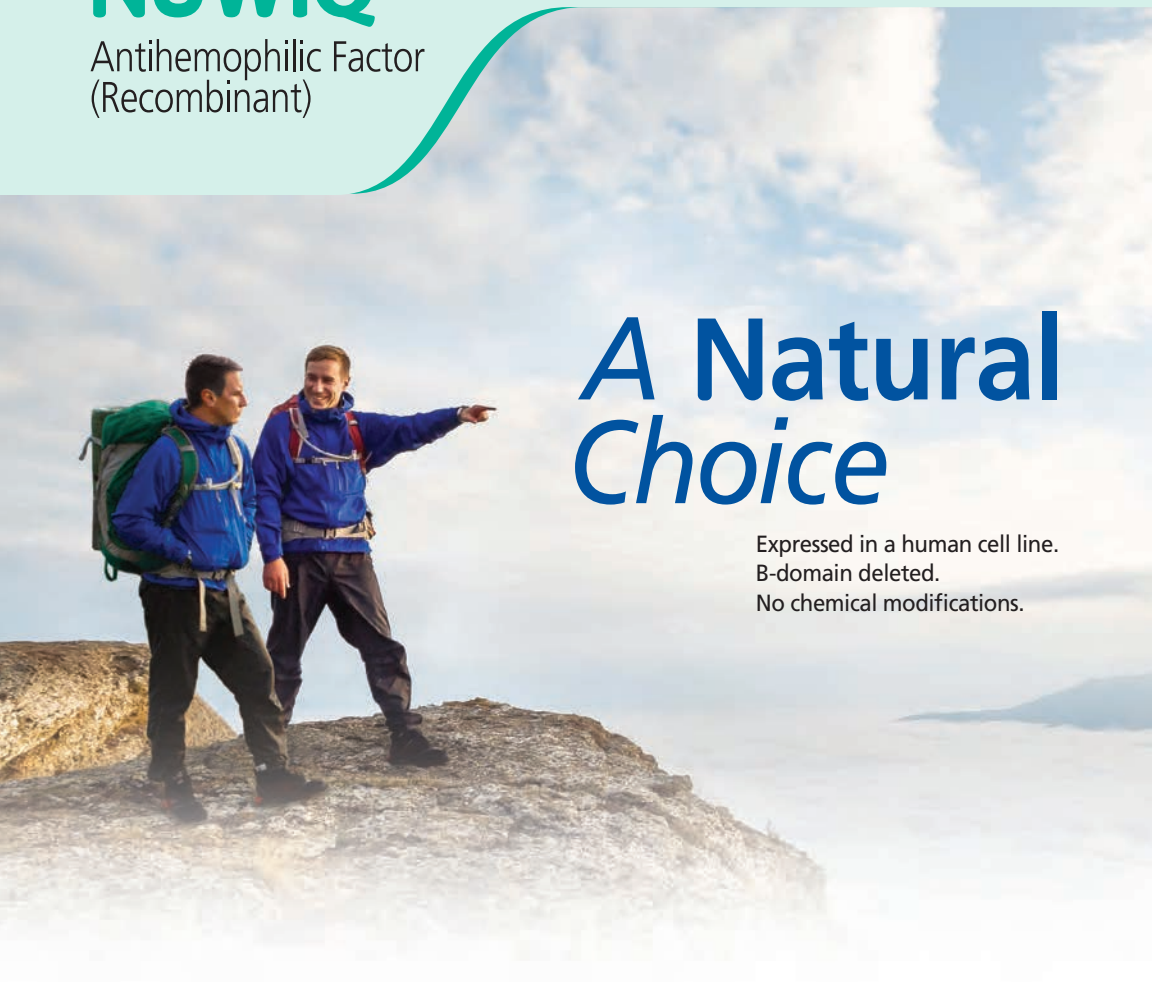
NUWIQ®

Antihemophilic Factor
(Recombinant)



A **Natural** *Choice*

Expressed in a human cell line.
B-domain deleted.
No chemical modifications.

Information for
Patients, Parents, & **Caregivers**

www.NUWIQUSA.com

Please see accompanying full Prescribing Information.

Please see Indications and Usage on page 2 and Important Safety Information throughout.

octapharma

Factor VIII Replacement:
The Foundation of Hemophilia Treatment

Hemophilia A is an inherited bleeding disorder that results from a deficiency of coagulation Factor VIII (FVIII).[1] It's only natural then, that the management of hemophilia A is generally based on the replacement of the missing FVIII.

In the 1950s and early 1960s, the only treatment options for people with hemophilia A were transfusions of whole blood or fresh frozen plasma. These transfusions contained the naturally occurring FVIII from people who didn't have hemophilia. By the 1970s, freeze-dried powdered FVIII concentrates became available. These factor concentrates could be stored at home. This allowed patients to self-infuse and avoid trips to the hospital.

Advancing Hemophilia Treatment

A new era in the management of hemophilia A began in 1984 when the FVIII gene was first cloned.[1] This would lead to the first genetically engineered FVIII molecules produced in hamster cell lines.[1] These products, called recombinant FVIII (rFVIII), would become the mainstay of hemophilia treatment for the next 20 years.

In 2015, Octapharma introduced a new treatment for hemophilia A—NUWIQ, a rFVIII product that is produced using a human cell line, not a hamster cell line. Because NUWIQ production cells are human, the protein produced more closely resembles the FVIII that is produced naturally in the human body.[2,3]

Indications and Usage
NUWIQ® is a recombinant antihemophilic factor [blood coagulation factor VIII (Factor VIII)] indicated in adults and children with Hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and for routine prophylaxis to reduce the frequency of bleeding episodes. NUWIQ is not indicated for the treatment of von Willebrand Disease.

Please see Important Safety Information.

Factor VIII Is the **Standard of Care**

FVIII replacement therapy is the standard of care for hemophilia A.[1] FVIII replacement is a trusted therapy that has been proven to be safe and effective over decades of use.

The way that FVIII works in the body is well understood by the doctors and nurses who prescribe it. And measuring FVIII levels with routine laboratory testing has helped make replacement therapy with FVIII the standard of care for hemophilia A.

Important Safety Information
NUWIQ is contraindicated in patients who have manifested life-threatening hypersensitivity reactions, including anaphylaxis, to the product or its components. The formation of neutralizing antibodies (inhibitors) to Factor VIII can occur following the administration of NUWIQ.

Please see accompanying full Prescribing Information.

NUWIQ®
Antihemophilic Factor (Recombinant)

A **Natural** *Choice*

Expressed in a human cell line. B-domain deleted. No chemical modifications.

www.NUWIQUSA.com

Have You Been Thinking About **Switching Your Hemophilia A Treatment?**

Today, many treatment choices are available, so you might be thinking about switching your hemophilia A treatment. Working together with your physician to choose a product that's right for you is one of the biggest decisions you'll ever make. The questions in this brochure are designed to help with your decision-making process.

How well do you really know the treatment you're currently using?

There are lots of things you should know about your current treatment. For example:

- How does your treatment work?
- How safe is it?
- How well did it perform in clinical studies?

Check out the product information and key facts about your current treatment. Things like how the product is made, the annual bleeding rate (ABR), and its safety record are very important considerations.

What matters most to you in choosing your hemophilia A treatment?

Consider the following:

- The source of cells used to make the product. Is it made from animal cells or human cells?
- Effective bleeding control. What is the ABR?
- Safety concerns. Are you worried about inhibitors? Are you concerned about switching FVIII products?
- Convenience. How important is dosing flexibility?

Important Safety Information
The formation of neutralizing antibodies (inhibitors) to Factor VIII can occur following the administration of NUWIQ®. Monitor all patients for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. If the plasma Factor VIII level fails to increase as expected, or if bleeding is not controlled after NUWIQ administration, suspect the presence of an inhibitor (neutralizing antibody).

Please see Important Safety Information.

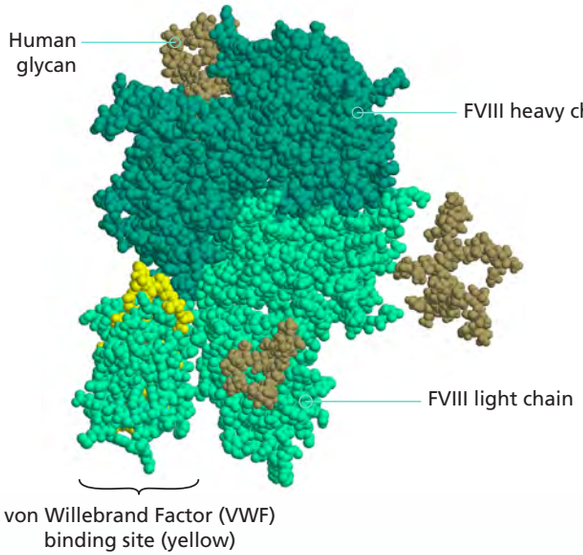
Consider NUWIQ—A *Natural* Choice

NUWIQ is a rFVIII treatment produced using a human cell line, not a hamster cell line. In fact, no animal or human proteins are added during manufacturing.[2,3]

NUWIQ Offers the Following Benefits[5-7]:

- Powerful bleeding control in adults and children
- Zero inhibitors in previously treated patients (PTPs) who switched to NUWIQ
- Low rate of inhibitors in previously untreated patients (PUPs)
- The potential to extend your dosing interval with personalized prophylaxis
- Available in a wide range of dosage strengths for individual dosing needs

NUWIQ Closely Resembles Natural FVIII Produced in the Human Body[1,2,5,8]



Please see accompanying full Prescribing Information.

NUWIQ®
Antihemophilic Factor (Recombinant)

A* Natural *Choice

Expressed in a human cell line. B-domain deleted. No chemical modifications.

www.NUWIQUSA.com

Powerful Bleeding Control With NUWIQ

How well does your current rFVIII product control your bleeding?

NUWIQ Was Proven to Control Bleeding in Adults and Children[5]

Prophylaxis treatment with NUWIQ was shown in studies to be effective for reducing the frequency of bleeding episodes in adults and children with severe hemophilia A.

SPONTANEOUS BLEEDS in ADULTS

in a study with 32 adults treated with prophylaxis for 6 months or more[5]

- Median ABR for all bleeds was **0.9**

SPONTANEOUS BLEEDS in CHILDREN

in a study with 59 children treated with prophylaxis for 6 months or more[5]

- Median ABR for all bleeds was **1.9**

Important Safety Information
The most common adverse reactions (>5% of subjects) reported in clinical trials were upper respiratory tract infection, headache, fever, cough, lower respiratory tract infection, rhinitis, chills, abdominal pain, arthralgia, anemia, and pharyngitis.

Please see Important Safety Information.

What Makes NUWIQ Different From rFVIII Products Made From Hamster Cell Lines?

Did you know that many rFVIII products, and some nonfactor products, are made from hamster cell lines?

NUWIQ Is a rFVIII Produced in a Human Cell Line

NUWIQ is not made from a hamster cell line, but from a human cell line. Because NUWIQ is produced in a human cell line and more closely resembles natural, human FVIII, the immune system may be less likely to see it as foreign and make antibodies against it.[2]

Please see accompanying full Prescribing Information.

NUWIQ®
Antihemophilic Factor (Recombinant)

A* Natural *Choice

Expressed in a human cell line. B-domain deleted. No chemical modifications.

www.NUWIQUSA.com

Understanding Inhibitor Risk

Are you concerned about developing inhibitors if you switch products?

Current evidence shows that switching FVIII products in PTPs carries minimal risk for inhibitor development. Among patients who have been previously treated with FVIII (>150 exposures), inhibitor risk from switching to a new product is less than 1%.[4]

ZERO
Inhibitors after switching to NUWIQ

NUWIQ Was Not Associated With the Development of Inhibitors in PTPs

In studies that included 135 PTPs, no patients treated with NUWIQ developed inhibitors.[5]

Low Rate of Inhibitors With PUPs[5,9*]

The safety and efficacy of NUWIQ in PUPs with severe hemophilia A was studied in a trial called *NuProtect*. The trial evaluated 105 PUPs, making *NuProtect* the largest prospective study ever done with a single FVIII product. Treatment duration was 100 exposure days (EDs) or a maximum of 5 years.

The final results showed an **absolute incidence** of high-titer inhibitors of **16.2%** and a **cumulative incidence** of **17.6%**.

16.2%
Absolute Incidence of High-Titer Inhibitors

Inhibitors in PUPs Treated With rFVIII Products Made From Hamster Cells

The **Survey of Inhibitors in Plasma-Product Exposed Toddlers**, or **SIPPET**, compared the rates of inhibitors in PUPs treated with plasma-derived FVIII (pdFVIII) or rFVIII made from a hamster cell line.[9]

Results from the SIPPET study showed that PUPs treated with rFVIII products from a hamster cell line had a higher incidence of inhibitor development than PUPs who had been treated with pdFVIII.[10†]

HIGH-TITER INHIBITORS — **28.4%** in PUPs treated with rFVIII from a hamster cell line

HIGH-TITER INHIBITORS — **18.6%** in PUPs treated with pdFVIII

*Information from the *NuProtect* study is presented in parallel to the SIPPET study for context, but please note that these trials were performed under different conditions and with different populations. The observed incidence of inhibitor formation may be influenced by a number of factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease.

†Differences in high-titer inhibitor rates between pdFVIII and rFVIII were not found to be statistically significant. SIPPET authors suggested this may have been due to the small sample size of the study.

Safety With NUWIQ

How safe is your current treatment?

NUWIQ was shown to be safe in clinical studies that included 135 PTPs.[5]

- No patients experienced serious adverse reactions to NUWIQ
- No patients experienced anaphylaxis, a very serious allergic reaction
- No patients dropped out of the study because of an adverse reaction to NUWIQ
- No deaths were reported

Important Safety Information
NUWIQ® is contraindicated in patients who have manifested life-threatening hypersensitivity reactions, including anaphylaxis, to the product or its components. The formation of neutralizing antibodies (inhibitors) to Factor VIII can occur following the administration of NUWIQ.

Please see Important Safety Information.
Please see accompanying full Prescribing Information.

NUWIQ®
Antihemophilic Factor (Recombinant)

A **Natural** *Choice*

Expressed in a human cell line. B-domain deleted. No chemical modifications.

www.NUWIQUSA.com

Dosing Flexibility With NUWIQ

Are you interested in the possibility of fewer weekly infusions?

The *NuPreviq* trial confirmed that personalized prophylaxis with NUWIQ is effective. Patients in the study were PTPs with severe hemophilia A. The majority of these patients achieved **twice-weekly infusions while maintaining bleeding control.**[7]

Does your treatment offer a wide range of dosage strength vials?

Having more vial options allows for simple dosing. For example, a patient who requires 2500 IU can use one 2500 IU vial instead of having to use a 2000 IU vial and a 500 IU vial.


250 IU


500 IU


1000 IU


1500 IU


2000 IU


2500 IU


3000 IU


4000 IU

- Low 2.5 mL diluent volume across the entire range of vial strengths

Important Safety Information
The most common adverse reactions (>5% of subjects) reported in clinical trials were upper respiratory tract infection, headache, fever, cough, lower respiratory tract infection, rhinitis, chills, abdominal pain, arthralgia, anemia, and pharyngitis.

Please see Important Safety Information.

octapharma

A **Trusted and Reliable Source** of FVIII Therapy

Since its founding in 1983, Octapharma has remained true to its principle of enhancing the lives of patients around the world. Today, Octapharma is the largest privately-owned protein products manufacturer in the world.

Octapharma was the first company to apply the solvent/detergent virus inactivation process to the routine production of FVIII concentrates.

Octapharma was also the first company to introduce a rFVIII that's produced in human cells *without chemical modification or fusion with any other protein*. That product is NUWIQ.

factor my way™

Resources for patients and caregivers, support for those navigating care, reliable educational materials, and uplifting community connection.

Factor My Way Assistance
Free trial, co-pay assistance, & real-world insurance know-how for eligible patients.

Factor My Way Connection
Meet experts and join our online support community to help you access resources and build relationships.

Factor My Way Events
Join scheduled live and on-demand digital information programs and events.

Factor My Way Learning
Learn-as-you-go, practical information about bleeding disorders, treatment, and lifestyle management.

Membership in Factor My Way is complimentary and open to anyone in the USA.

Join the program at www.factormyway.com, or call 1-855-498-4260.

Please see accompanying full Prescribing Information.

NUWIQ®
Antihemophilic Factor (Recombinant)

A* Natural *Choice

Expressed in a human cell line. B-domain deleted. No chemical modifications.

www.NUWIQUSA.com

NUWIQ®

Antihemophilic Factor (Recombinant)

A **Natural** *Choice*

Expressed in a human cell line.
B-domain deleted.
No chemical modifications.

NUWIQ is the Only Recombinant FVIII Produced Using a Human Cell Line Without Chemical Modification or Protein Fusion

LOW INHIBITORS

Zero inhibitors in PTPs

In PUPs:

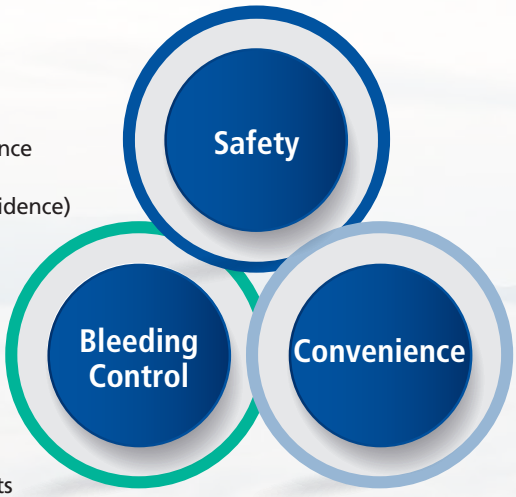
16.2% absolute incidence of high-titer inhibitors (**17.6%** cumulative incidence)

ZERO

Median ABR Spontaneous Bleeds

Prophylaxis in adults and children treated for ≥6 months

Median ABR for all bleeds was **0.9** in adults and **1.9** in children



DOSING FLEXIBILITY

Broad range of vial sizes
250, 500, 1000, 1500, 2000, 2500, 3000, and 4000 IU

2.5 mL diluent volume across ALL vials

Potential for **2x weekly infusions** with personalized prophylaxis

Easy monitoring by chromogenic or one-stage assay

www.NUWIQUSA.com

Octapharma USA, Inc.
117 W. Century Road
Paramus, NJ 07652
Tel: 201-604-1130

Medical Affairs
usmedicalaffairs@octapharma.com

For all inquiries relating to drug safety, or to report adverse events, please contact our Local Drug Safety Officer:

Tel: 201-604-1137 | **Cell:** 201-772-4546 | **Fax:** 201-604-1141
or contact the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**

Important Safety Information

NUWIQ® is contraindicated in patients who have manifested life-threatening hypersensitivity reactions, including anaphylaxis, to the product or its components. Hypersensitivity reactions, including anaphylaxis, are possible with NUWIQ. The formation of neutralizing antibodies (inhibitors) to Factor VIII can occur following the administration of NUWIQ.

References: 1. Cafuir LA, et al. Ther Adv Hematol. 2017;8(10):303–313. **2.** Sandberg H, et al. Thromb Res. 2012;130(5):808-817. **3.** Casademunt E, et al. Eur J Haematol. 2012;89(2):165-176. **4.** Matino D, et al. Haemophilia. 2014;20(2):200-206. **5.** NUWIQ full Prescribing Information. Paramus, NJ: Octapharma; rev 2021. **6.** Data on file. Paramus, NJ: Octapharma USA Inc; 2019. **7.** Lissitchkov T, et al. Haemophilia. 2017;23(5):697-704. **8.** Kannicht C, et al. Thromb Res. 2013;131(1):78-88. **9.** Liesner R, et al. Thromb Haemost. Published online Feb 13, 2021. doi:10.1055/s-0040-1722623. **10.** Peyvandi F, et al. N Engl J Med. 2016;374(21):2054-2064.

Please see accompanying full Prescribing Information.

Date of preparation: 7/2022. NUW-0593-COT

octapharma