My treatment *goals + questions*

Before every office visit, it's helpful to make a list of goals and questions about your condition and treatment to discuss with your healthcare team. Below are some of the common questions patients and caregivers often ask.

Bleeding Prevention & Control

- ☐ I'm interested in being "bleed-free". Could NUWIQ help keep me "bleed-free"?
- ☐ I take / my child takes clotting factor as prophylaxis. What factor products offer effective bleed protection? Does NUWIQ offer effective bleed protection?
- ☐ I / my child treats on-demand. What factor products resolve bleeds most effectively? How effective is NUWIQ at resolving bleeds?

Inhibitors & Safety

- ☐ My child is a PUP (previously untreated patient). Should I be concerned about inhibitors if we start treatment with a clotting factor?
- ☐ Is there a difference between hamster cell line-derived and human cell line-derived factor products? Do human cell line-derived factor products result in lower inhibitor rates than hamster cell line-derived products? Is NUWIQ hamster cell line-derived or human cell line-derived?
- ☐ I'm an adult PTP (previously treated patient) but I've heard that switching factor products may lead to inhibitors. Is there a risk of developing inhibitors if I switch products? Could NUWIQ be an option for me?

Dosing & Convenience

- ☐ What is personalized or individualized prophylaxis? Can it help reduce the number of weekly infusions? Can I achieve fewer infusions with NUWIQ?
- ☐ My factor dose is high. I need higher dosage strength vials. Does NUWIQ offer higher dosage strength vials?
- ☐ I infuse several times a week, so a low diluent volume is very important to me. What is the diluent volume for NUWIQ?
- ☐ Does NUWIQ offer free trial and co-pay assistance programs?

NUWIQ®
Antihemophilic Factor (Recombinant)

A Natural *Choice*

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

ZERO
Median ABR
Spontaneous Bleeds

Prophylaxis in adults and children treated for ≥6 months

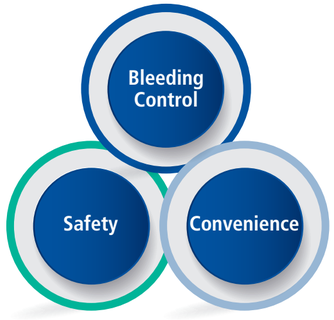
Median ABR for all bleeds was **0.9** in adults and **1.9** in children

LOW INHIBITORS

Zero inhibitors in PTPs in a clinical trial

In PUPs:

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



DOSING FLEXIBILITY

Broad range of vial sizes
250, 500, 1000, 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

factor my way™

Strength, Support & Community for People Living with Bleeding Disorders

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.

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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
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.

References: 1. NUWIQ full Prescribing Information. Paramus, NJ: Octapharma USA, Inc.; rev 2020. **2.** Lissitchkov T, et al. Haemophilia. 2017;23:697-704. **3.** Valentino LA, et al. Haemophilia. 2014;20(suppl 1):1–9. **4.** Kessler C, et al. Haemophilia. 2015;21(suppl 1):1–12. **5.** Lissitchkov T, et al. Haemophilia. 2016;22:225-231. **6.** Liesner R, et al. Thromb Haemost. Published online Feb 13, 2021. doi:10.1055/s-0040-1722623. **7.** Peyvandi F, et al. N Engl J Med. 2016;374:2054-2064. **8.** Sandberg H, et al. Thromb Res. 2012;130(5):808-817. **9.** Casademunt E, et al. Eur J Haematol. 2012;89(2):165-176. **10.** Matino D, et al. Haemophilia. 2014;20(2):200-206. **11.** Data on file. Paramus, NJ: Octapharma USA, Inc. **12.** Shapiro AD, et al. Haemophilia. 2005;11:571-582.

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Talking to your healthcare team about **NUWIQ**

NUWIQ®
Antihemophilic Factor (Recombinant)

A Guide to Help Patients, Parents, & Caregivers Have Productive Conversations With Their Healthcare Providers

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.

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

Please see accompanying full Prescribing Information.

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Frequently Asked Questions About NUWIQ®

Bleeding Prevention & Control

I take / my child takes clotting factor as prophylaxis. Does NUWIQ offer effective bleed protection?

- Prophylaxis with NUWIQ (every other day or 3 times per week for 6 months or more) was highly effective at reducing the frequency of bleeding episodes in studies of adults (n = 32) and children (n = 59) with severe hemophilia A[1]
  - **All Bleeds:** median ABR (annualized bleeding rate) was **0.9** in adults and **1.9** in children
  - **Spontaneous Bleeds:** median ABR for adults and children was **ZERO**
- In a study of personalized prophylaxis for 6 months with NUWIQ in 66 PTPs, median ABR for **All Bleeds** was **ZERO**, including spontaneous bleeds, traumatic bleeds, and joint bleeds[2]

I / my child treats on-demand. How effective is NUWIQ at resolving bleeds?

- On-demand treatment with NUWIQ provided effective resolution of bleeding in adults who treated for 986 spontaneous or traumatic bleeds[3-5]
  - **94%** of on-demand responses rated as "excellent" or "good"
  - **90%** of bleeds resolved with just **1 infusion**; **97%** resolved with **2 infusions**

How effectively does NUWIQ control breakthrough bleeds?

- In cases of breakthrough bleeding episodes in adults (n = 15 with 30 bleeding episodes) and children (n = 32 with 108 bleeding episodes)[1]
  - Efficacy was "excellent" or "good" in **100%** of bleeds in adults and **82%** of bleeds in children
  - Median number of NUWIQ injections to treat a bleeding episode was **1**

How well does NUWIQ prevent bleeds with surgery?

- NUWIQ was shown to provide highly effective prevention and control of bleeding during and after surgery. Among 33 surgical procedures conducted in 19 patients[1]:
  - In **100%** of minor surgeries, bleeding control was rated as "excellent"
  - In **92%** of major surgeries, bleeding control was rated as "excellent" or "good"

Important Safety Information
Hypersensitivity reactions, including anaphylaxis, are possible with NUWIQ. Early signs of hypersensitivity reactions that can progress to anaphylaxis may include angioedema, chest tightness, dyspnea, wheezing, urticaria, or pruritus. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.
Please see accompanying full Prescribing Information.

Inhibitors & Safety

*My child is a PUP. What is NUWIQ's inhibitor rate in PUPs?**

- In a study called ***NuProtect***, 105 PUPs with severe hemophilia A received NUWIQ for 100 EDs (exposure days) or a maximum of 5 years. Final results are complete and show a relatively low incidence of inhibitors[2,6]
  - Incidence of all inhibitors was **26.7%** and high-titer inhibitors was **16.2%**
- In a well-known study called SIPPET, 126 PUPs were treated with hamster cell line-derived recombinant FVIII (rFVIII) and 125 with plasma-derived FVIII (pdFVIII)[7]
  - For rFVIII, incidence of all inhibitors was **37.3%** and high-titer inhibitors was **23.8%**
  - With pdFVIII, incidence of all inhibitors was **23.2%** and high-titer inhibitors was **16%**

What makes NUWIQ different from other clotting factor products?

- NUWIQ is different from rFVIII derived from hamster cell lines, because those products may contain small amounts of animal proteins[8]
  - The immune system may see these proteins as foreign and produce antibodies (inhibitors) against them. Inhibitors can impair the ability of FVIII to control bleeding
- NUWIQ closely resembles the natural FVIII that is produced in the body. It is the only rFVIII derived from a human cell line without chemical modification or protein fusion[1,8,9]

I'm an adult PTP. Is there a risk of developing inhibitors if I switch products? Could NUWIQ be an option for me?

- Current evidence shows that switching FVIII products carries a **very low risk** of inhibitor development.[10] In NUWIQ studies that included 135 PTPs, **ZERO** patients who switched to NUWIQ from other FVIII products developed inhibitors[6]

How safe is NUWIQ? Have any serious adverse reactions been reported?

- NUWIQ was shown to be safe and well tolerated in studies that included 135 PTPs[1,11]
  - No patients experienced serious adverse reactions or anaphylaxis (a very serious allergic reaction)
  - No patients stopped treatment because of an adverse reaction to NUWIQ

*Results from the ***NuProtect*** study are 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. In the SIPPET study, differences in high-titer inhibitor rates between pd-FVIII and rFVIII were not found to be statistically significant.

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 accompanying full Prescribing Information.

Dosing & Convenience

What is personalized or individualized prophylaxis? Can it help reduce the number of weekly infusions?

- Personalized prophylaxis is a treatment method where your FVIII dose and dosing frequency are customized to your unique pharmacokinetics. Personalized prophylaxis has the potential to reduce the number of infusions
- Pharmacokinetics, or PK, describes how coagulation factors, like FVIII, are absorbed, distributed through the body, and eliminated. A PK test can help your doctor determine your ideal starting dose, maintenance dose, and dosing interval (how often you need to infuse)[12]

Can I infuse 2 times per week with NUWIQ?

- In a recent trial called ***NuPreviq***, personalized prophylaxis with NUWIQ enabled the majority of patients to extend their dosing interval to twice weekly or less[2]
  - 57% of patients achieved 2x weekly or less. Median dosing interval was 3.5 days

My factor dose is high. Does NUWIQ offer higher dosage strength vials?

- NUWIQ offers flexible dosing for children and adults, and a wide range of dosage strength vials: 250 IU, 500 IU, 1000 IU, 2000 IU, 2500 IU, 3000 IU, 4000 IU[1]

A low diluent volume is very important to me and/or my child. Does NUWIQ offer a low diluent volume?

- NUWIQ offers a low 2.5 mL diluent volume across the entire range of vial strengths. This is the lowest diluent volume among all currently approved FVIII products[1]

Does NUWIQ offer free trial and co-pay assistance programs?

- The **Factor My Way** program from Octapharma provides a wealth of resources for patients and caregivers, including free trial and co-pay assistance for eligible patients (*see back panel for more information*.)

Important Safety Information
The most frequently occurring adverse reactions (>0.5%) in clinical trials were paresthesia, headache, injection site inflammation, injection site pain, non-neutralizing anti-Factor VIII antibody formation, back pain, vertigo, and dry mouth.
Please see accompanying full Prescribing Information.

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Antihemophilic Factor (Recombinant)
A **Natural** *Choice*
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www.NUWIQUSA.com