PART III: CONSUMER INFORMATION

Nuwiq®

Antihemophilic Factor (Recombinant, B-Domain deleted)

This leaflet is part III of a three-part "Product Monograph" published when Nuwiq® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Nuwiq®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Nuwiq® is used for treatment and prophylaxis of bleeding in patients with hemophilia A (congenital factor VIII deficiency).

Nuwiq® is appropriate for use in adults and children of all ages.

What it does:
Nuwiq® contains the active substance Antihemophilic Factor (Recombinant, B-Domain deleted), simoctocog alfa. Factor VIII is necessary for the blood to form clots and stop bleedings. In patients with hemophilia A (inborn factor VIII deficiency), factor VIII is missing or not working properly and these patients tend to bleed easily or for prolonged periods of time. Nuwiq® is injected into veins of patients with hemophilia A to help prevent bleeding from occurring or to treat bleeding that had already begun. When Nuwiq® is administered, it circulates in the blood and the body begins to use it right away to form a blood clot.

When it should not be used:
Nuwiq® should not be used if you are allergic to simoctocog alfa or any of the other ingredients of this medicine. If you are unsure about this, ask your doctor.

What the medicinal ingredient is:
Antihemophilic Factor (Recombinant, B-Domain deleted)

Nuwiq® is a coagulation factor VIII product that is produced by recombinant technology.
No animal- or human-derived materials are added during the manufacturing process or to the final product, making it naturally free from the risk of transmission of blood-borne pathogens.

What the important non-medicinal ingredients are:
Sucrose, sodium chloride, calcium chloride, arginine hydrochloride, sodium citrate and poloxamer 188 and solvent (water for injection).
Nuwiq® does not contain any preservatives.

What dosage forms it comes in:
Powder and solvent for solution for intravenous injection. One package of Nuwiq® contains:
One powder vial (250 IU FVIII, 500 IU FVIII, 1000 IU FVIII, 2000 IU FVIII, 2500 IU FVIII, 3000 IU FVIII or 4000 IU FVIII) and a pre-filled syringe containing the solvent (2.5 mL water for injection).

WARNINGS AND PRECAUTIONS

BEFORE you use Nuwiq® talk to your doctor or pharmacist if:

- you are pregnant or nursing.
- you will be undergoing any scheduled surgical procedures.
- you have had inhibitor development in the past.
- you are allergic to the active substance or to any of the nonmedical ingredients.

Your body may produce antibodies (or inhibitors) to factor VIII, which may prevent Nuwiq® from working properly. Inhibitors are a known complication of hemophilia treatment and can develop in anyone, but are most common in young children. If your bleeding is not controlled with your usual dose of Nuwiq®, contact your hemophilia doctor or nurse. You should be monitored for the presence of inhibitors.

INTERACTIONS WITH THIS MEDICATION

There is no known drug interaction with Nuwiq®.

PROPER USE OF THIS MEDICATION

Usual dose:
As dosage and treatment duration depend on your clinical situation, the type and severity of your bleeding and your FVIII:C levels, your physician will decide on your treatment on an individual basis.

General dosing recommendations:

- For a minor bleeding episode: 20–40 IU/kg body weight.
- For a moderate/major bleeding episode: 30–60 IU/kg body weight.
- For a life-threatening bleeding episode: 60–100 IU/kg body weight.
- For a minor surgical procedure: 30–60 IU/kg body weight for at least 1 day.
- For a major surgical procedure: 80–100 IU/kg body weight before and after surgery.
- Long-term prophylaxis against bleeding for adults is 30−40 IU/kg of body weight every other day.
- Regular prophylaxis schedule for children is 30−40 IU/kg of body weight every other day or 3 times per week.

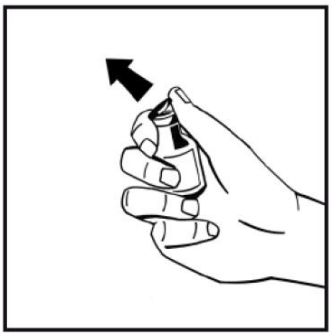
Overdose:
No symptom of overdose has been reported.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

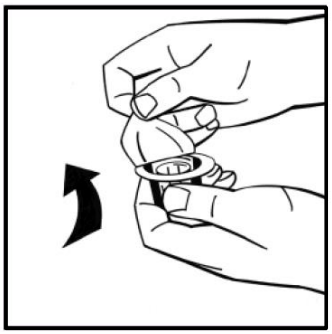
Missed Dose:
It is important to take the total daily dose prescribed to ensure you get maximum benefit. If you miss a dose, take the missed dose as soon as possible, and then continue as before. However, if a dose is skipped, do not double the next dose. Continue on with your normal dose on the regular schedule as prescribed by your doctor.

Instructions for mixing and injecting Nuwiq®:

1. Allow the solvent (water for injection) in the syringe and the concentrate in the closed vial to reach room temperature. This temperature should be maintained during reconstitution.
2. Remove the plastic flip-top cap from the concentrate vial to expose the central portions of the rubber stopper. Do not remove the gray stopper or metal ring around the top of the vial.

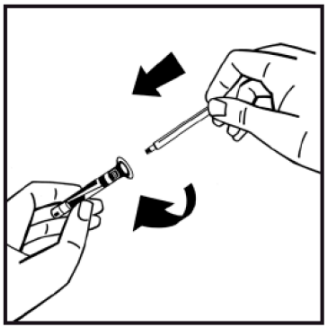


3. Wipe the top of the vial with an alcohol swab (not provided). Allow the alcohol to dry.
4. Peel back the paper cover from the vial adapter package. Do not remove the adapter from the package.

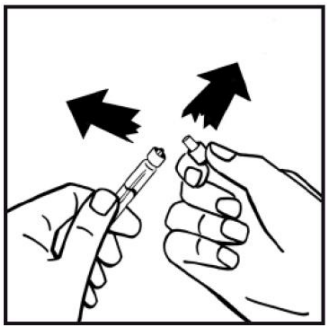


5. Place the concentrate vial on an even surface and hold it. Take the adapter package and place the vial adapter over the centre of the rubber stopper of the concentrate vial. Press down firmly the adapter package until the adapter spike penetrates the rubber stopper. The adapter snaps to the vial when done.

6. Peel back the paper cover from the prefilled syringe package. Take the plunger rod at the end and avoid contact with the shaft. Attach the threaded end of the plunger rod to the solvent syringe plunger. Turn the plunger rod clockwise until a slight resistance is felt.

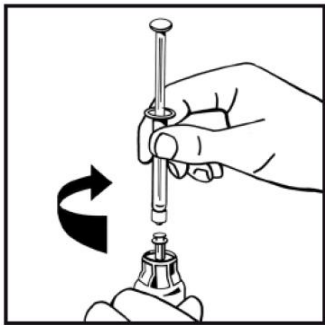


7. Break off the tamper-proof plastic tip from the solvent syringe by snapping the perforation of the cap. Do not touch the inside of the cap or the syringe tip.

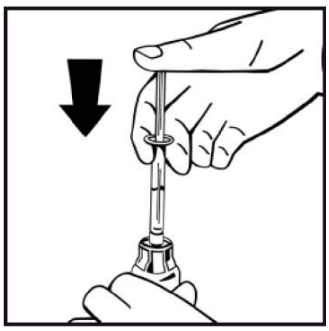


8. Remove the adapter package and discard.

9. Firmly connect the solvent syringe to the vial adapter by turning clockwise until resistance is felt.

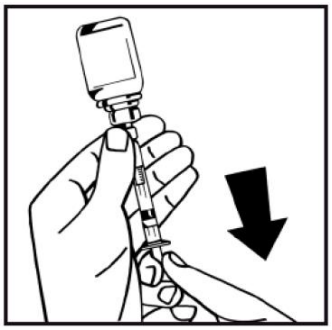


10. Slowly inject all solvent into the concentrate vial by pressing down the plunger rod.



11. Without removing the syringe, dissolve the concentrate powder by gently moving or swirling the vial in circles a few times. DO NOT SHAKE. Wait until all the powder dissolves completely.

12. Inspect the final solution for particles before administration. The solution should be clear and colourless, practically free from visible particles. Do not use solutions that are cloudy or have deposits.
13. Turn the vial attached to the syringe upside down and slowly draw the final solution into the syringe. Make sure that the entire content of the vial is transferred to the syringe.



14. Detach the filled syringe from the vial adapter by turning counter clockwise and discard the empty vial.

Nuwiq® should be administered using the pre-filled solvent syringe as provided with your product.
If more than one vial of Nuwiq® is used per injection, each vial should be dissolved according to the instructions in this section. A separate large sterile luer lock syringe may be used to collect the dissolved contents of each vial for infusion.
The reconstituted solution should always be transferred under aseptic conditions from the vial to the syringe using the vial adapter. The empty syringe should be removed leaving the vial adapter in place.
Do not detach the solvent syringes or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial adapter or to the infusion set.

The solution is now prepared for immediate use or within 3 hours after reconstitution. In case the solution is not used immediately close the filled syringe with the tamper-proof plastic tip for storage. Do not refrigerate the solution after reconstitution.

15. Clean the chosen injection site with an alcohol swab (not provided).
16. Attach the provided infusion set to the syringe. Insert the needle of the infusion set into the chosen vein. If you have used a tourniquet to make the vein easier to see, this tourniquet should be released before you start injecting the solution. No blood must flow into the syringe due to the risk of formation of fibrin clots.
17. Inject the solution into the vein at a rate of 4 mL per minute.
18. After the infusion, remove the peel-off label containing the batch number from the factor concentrate vial and place it in your factor log book.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Allergic reactions such as hives and itching can occur at the injection site with Nuwiq®. If these symptoms occur contact your doctor or pharmacist for advice before continuing treatment.
In rare cases, the allergic reactions are severe, known as shock or anaphylactic shock. This may include extreme difficulty breathing, or loss of consciousness. Urgent treatment is required and the emergency services should be called, for example 911.

You should tell your doctor if you have been previously treated with factor VIII products, especially if you developed inhibitors, since there might be a higher risk that it happens again. Inhibitors are blocking antibodies against factor VIII that reduce the efficacy of Nuwiq® in prevention or control of bleeding. Development of inhibitors is a known complication in the treatment of hemophilia A. If your bleeding is not controlled with Nuwiq®, tell your doctor immediately. Tests should be performed to determine if the inhibitors are present.
This is not a complete list of side effects. For any unexpected effects while taking Nuwiq®, contact your doctor or pharmacist.

HOW TO STORE IT

Store Nuwiq® and solvent in a refrigerator at +2°C to +8°C until the indicated expiry date. Nuwiq® may be stored at room temperature (up to 25°C) for up to one month not to exceed the expiry date. Please record the date from when you start to store Nuwiq® at room temperature on the product carton. Do not store Nuwiq® in the refrigerator again after it has been stored at room temperature.
The powder should be reconstituted only directly before injection. The reconstituted solution should be used on one occasion only. Use the reconstituted solution immediately or within 3 hours after reconstitution. Keep the reconstituted solution at room temperature. Do not refrigerate after reconstitution. Any solution remaining should be discarded.
Keep the vial in the outer carton in order to protect from light.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
www.octapharma.ca
or by contacting Octapharma Canada Inc.,
at: 1-888-438-0488

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