Patient leaflet: Information for the user

Dried Factor VIII Fraction Type 8Y 25 IU/ml powder for solution for injection

human coagulation factor VIII and von Willebrand Factor (VWF)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What 8Y is and what it is used for

8Y is a concentrate of factor VIII and von Willebrand factor (VWF) prepared from human plasma (the liquid part of the blood) and then heat treated.

8Y is used for all age groups to prevent and treat bleeding caused by the lack of factor VIII in haemophilia A. 8Y is also used and to prevent and treat bleeding caused by the lack of VWF in von Willebrand disease when treatment with another medicine, desmopressin, is not effective on its own or cannot be given.

Factor VIII and VWF are involved in blood clotting. Lack of either factor means that blood does not clot as quickly as it should so there is an increased tendency to bleed. The replacement of factor VIII or VWF by 8Y will temporarily restore the blood clotting mechanisms.

Your doctor will explain further why this medicine has been given to you.

Summary of Contents

Vial Size of 8Y	**Factor VIII potency[2]**	**VWF potency[3]**
250 IU[1]	250 IU/Vial	500 IU/Vial
500 IU[1]	500 IU/Vial	1000 IU/Vial

1 After reconstitution with appropriate amount of sterile water for injections (see Dissolving your medicine before use)
2 Potency complies with Ph.Eur. for human coagulation factor VIII
3 Potency complies with Ph.Eur. for human coagulation factor VIII for preparations intended for the treatment of von Willebrand's disease

2. What you need to know before you use 8Y

Do not use 8Y:
- if you are allergic to factor VIII or von Willebrand factor (VWF) or any of the other ingredients of 8Y (listed in section 6).

Warnings and precautions
Talk to your doctor before using 8Y if any of the following conditions applies to you:

- Allergic (hypersensitivity) reactions are possible. **If symptoms of hypersensitivity occur, you should stop using 8Y immediately and contact your doctor**. Your doctor should inform you of the **early signs of hypersensitivity reactions**. These include hives, generalised skin rash, tightness of the chest, wheezing, fall in blood pressure and anaphylaxis (a serious allergic reaction that causes severe difficulty in breathing, or dizziness).
- The formation of **inhibitors** (antibodies) is a known complication that can occur during treatment with all factor VIII medicines. These inhibitors, especially at high levels, stop the treatment working properly and you or your child will be monitored carefully for the development of these inhibitors. If you or your child's bleeding is not being controlled with 8Y, tell your doctor immediately.
- If you have been told you have heart disease or are at risk of heart disease or you **suffer from high blood pressure**, diabetes, have a history of cardiovascular disease or a blood/blood related disorder, tell your doctor or nurse before this medicine is injected.
- If for the administration of 8Y you require a central venous access device (CVAD), the risk of CVAD-related complications should be considered by your doctor.
- Von Willebrand disease
  If you have a known risk of developing blood clots, you must be monitored for early signs of thrombosis (blood clotting). Your doctor should give you treatment to prevent thrombosis.

Virus safety
When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:
- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded
- the testing of each donation and pools of plasma for signs of virus/infections
- the inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped hepatitis A virus. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals whose immune system is depressed or who have some types of anaemia (e.g. sickle cell disease or haemolytic anaemia).

It is strongly recommended that every time you receive a dose of 8Y, the name and batch number of the product are recorded to maintain a record of the batches used.

Your doctor may recommend that you consider vaccination against hepatitis A and B if you regularly or repeatedly receive human plasma-derived factor VIII products.

Children and adolescents
The listed warnings and precautions apply to both adults and children.

Other medicines and Optivate
Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
8Y does not affect your ability to drive or use machines.

8Y contains sodium
This medicine contains approximately 2.9 mg sodium (main component of cooking/table salt) per ml. This is equivalent to 0.15% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use 8Y

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- 8Y should be injected directly in a vein. Before injecting this medicine, you should have received training by your healthcare professional on how to do this.
- Use only the recommended provided injection equipment provided with your medicine.
- The dose should be given slowly (not more than 3 ml per minute).
- After making up the solution with water, the injection should be completed within one hour. The solution must not be stored.

How much 8Y to use
The amount of 8Y you need to use and the duration of treatment depend on:
- the severity of your disease
- the site and intensity of the bleeding
- your clinical condition
- your body weight

Your doctor will explain how much you should use and when you should use it. If further treatment is needed, doses may be repeated. You doctor will advise you if this is necessary.

Use in children and adolescents
Dosing in children and adolescents is based on body weight and therefore is generally based on the same instructions as for adults. In some cases, especially in younger patients, higher doses may be needed.

If you use more 8Y than you should
If you think you may be using too much, stop the injection and tell your doctor. If you know you have used too much, tell your doctor as soon as possible.

If you forget to use 8Y
Do not use a double dose to make up for a forgotten dose.

If you stop using 8Y
Always talk to your doctor before deciding to stop your treatment.

Reconstitution and application

Dissolving your medicine before use

1. 8Y must only be dissolved in the sterile water provided with the product.

Vial of 8Y	Quantity of Water
250 IU	10 ml
500 IU	20 ml

2. Before you remove the flip-off cap, make sure that the vial of 8Y and the container of water supplied with it are both at room temperature (between 20-30°C).
3. Remove the caps from the 8Y vial and the vial of sterile water.
4. Clean the tops of the vial stoppers with a spirit swab.
5. Either one of the following two methods can be used to transfer the water to the 8Y powder:

A. Pierce the stopper of the vial of sterile water with a needle (but not the filter needle) and syringe and draw up the required volume of water (see table). Transfer the water to the vial containing the powder by piercing the stopper with the needle which will automatically draw the water from the syringe into the vial as it is under vacuum. Remove the syringe from the needle before removing the needle from the vial of 8Y.

B. Remove the protective guard from one end of the transfer needle and push it through the stopper of the sterile water. Then turn these two upside down and remove the cover guard from the other end of the transfer needle. Push the vial of powder onto the transfer needle and the water will be drawn up into the vial of powder. When the water has finished moving into the vial of powder (there will be some water left in the water vial) first pull the water vial off the transfer needle before removing this needle from the vial of powder.

6. As the water enters the vial of powder, gently swirl the vial around to wet the powder, but do not shake it. Throw away any unused water.
7. Continue swirling the vial around gently until the powder is completely dissolved. A clear or slightly pearl-like solution should be obtained within 10 minutes.
8. The solution should be used immediately, and injection must be completed within one hour.
9. If you have to use more than one vial to make up your dose, you need to draw up the solution in each vial into one syringe for your injection, but you must use a new sterile filter needle to draw the contents of each vial up into the plastic syringe.
10. Only use the provided water for injection to make up the solution. Never inject the water on its own without the powder.

Do not use this medicine if the:

A. water is not pulled into the vial (this indicates a loss of vacuum in the vial, so the powder must not be used).
B. dissolved powder and sterile water form a gel or a clot (if this happens, please tell Bio Products Laboratory, reporting the batch number printed on the vial).
C. solution is cloudy or has bits in it.

Injecting the medicine

After the medicine is dissolved:

- Clean the stopper again with a spirit swab.
- Draw the medicine into a plastic, disposable syringe through the sterile filter needle provided (this will remove any tiny particles).
- To inject the medicine, attach a suitable needle or “butterfly” to the syringe.

- The dose, especially the first dose, should be given slowly (no more than 3 ml per minute) into your vein.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For children not previously treated with factor VIII medicines, inhibitor antibodies (see section 2) may form very commonly (more than 1 in 10 patients); however patients who have received previous treatment with factor VIII (more than 150 days of treatment) the risk is uncommon (less than 1 in 100 patients). If this happens you or your child's medicines may stop working properly and you or your child may experience persistent bleeding. If this happens, you should contact your doctor immediately.

Hypersensitivity or allergic reactions have been observed rarely in patients treated with factor VIII containing products. If you get any of the following symptoms, stop the injection and tell your doctor immediately:
- allergic type reactions. The early signs of this are nettle rash, tightness of the chest, wheezing, low blood pressure (light- headedness).
- an increase in body temperature.
- development of antibodies.

Occasionally flushing, nausea (feeling sick), coughing, slow or fast pulse rate, taste disturbance, drowsiness, blurred vision, headache and lower back pain are seen.

Patients with Blood groups A, B or AB receiving large doses should be tested for any evidence of destruction of the patients red blood cells.
VWD patients who develop bruising should stop injection immediately and contact the doctor.
If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Website: www.mhra.gov.co.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store 8Y

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the containers after "EXP". The expiry date refers to the last day of that month.

Store between 2°C-8°C in a refrigerator. Do not freeze.
Short periods (up to 3 months) of storage at room temperature (up to 25°C, but not higher). Keep the vials in the outer carton in order to protect from light.

Do not use this medicine if you notice small bits in the dissolved product. Once reconstituted, 8Y must be used immediately or no more than 1 hour.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist or doctor how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What 8Y contains
- The active substances are human coagulation factor VIII and von Willebrand factor (VWF).
- The excipients are: sodium chloride, trisodium citrate, trometamol, calcium chloride and sucrose.

What 8Y looks like and the contents of the pack
8Y is a white or pale yellow, crumbly, sterile powder, available as single dose vials containing either 250 IU or 500 IU in glass vials.
These vials are closed with a rubber stopper under vacuum, held with a tamper-evident cap.

8Y is supplied with a glass vial of water (10 ml or 20 ml, sterilised water for injections) to dissolve the medicine.

Marketing Authorisation Holder
Bio Products Laboratory Limited
Dagger Lane
Elstree
Hertfordshire
WD6 3BX
United Kingdom
tel: +44 (0) 20 8957 2255
e-mail: medinfo@bpl.co.uk

Manufacturer
Bio Products Laboratory Limited
Dagger Lane
Elstree
Borehamwood
WD6 3BX
United Kingdom

This leaflet was last revised in January 2021