Package Leaflet: Information for the User
Optivate 250 IU, 500 IU, 1000 IU
Powder and solvent for solution for injection

Human coagulation factor VIII

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. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Optivate is and what it is used for

Optivate is a high purity factor VIII concentrate from human blood plasma obtained from screened donors. It is a white or pale yellow sterile powder, supplied with sterilised water for injections.
Optivate is given by injection into a vein (intravenously) and is used to prevent and treat bleeding in patients with haemophilia A (congenital factor VIII deficiency in the blood). Your doctor will explain further why this medicine has been given to you.

2. What you need to know before you use Optivate

Do not use Optivate:
- if you are allergic (hypersensitive) to the human coagulation factor VIII or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
- If you have a larger or longer bleed than usual and the bleeding does not stop after an injection of Optivate, speak to your doctor.
Some patients with a shortage of factor VIII may develop inhibitors (antibodies) to factor VIII during treatment. This could mean that the treatment will not work properly. Your doctor will check regularly for the development of these antibodies, and especially before an operation. Both before and after treatment with this medicine, particularly for your first course of treatment, your doctor will probably carry out tests to check the level of factor VIII in your blood.
- This medicine may contain small amounts of blood group antibodies originally present in the plasma from the donors. This is normal and, in most cases, these antibodies do not cause any problems. However, if you need large doses of Optivate, for example during surgery, and are blood group A, B, or AB, your doctor may need to do a blood test to check if the medicine has had any effect on your red blood cells prescription.

Catheter-related complications: If a central venous access device (CVAD) is required, risk of CVAD-related complications including local infections, bacteraemia and catheter site thrombosis should be considered.

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 (fetal 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 Optivate, the name and batch number of the product are recorded in order to maintain a record of the batches used.

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

Other medicines and Optivate
These injections must not be mixed with other medicinal products in the same syringe. Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

Driving and using machines
There are no known effects of this product on the ability to drive or operate machinery.

3. How to use Optivate
Before injecting this medicine at home, you will have received training at your Haemophilia Centre on how to do so. Use only the recommended injection equipment provided with your medicine.
Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.
Your doctor will explain to you how much you should use and when you should use it.
Your doctor will usually tell you your dose in terms of the number of full vials nearest to the dose most suited to you.If further treatment is needed, doses may be repeated at intervals of 8, 12 or 24 hours, as required. Your doctor will advise you if this is necessary. The table gives the approximate doses of factor VIII which are needed to stop bleeding in various conditions:

Adults:

Condition	**Initial dose of Optivate (IU/kg bodyweight)**
Minor spontaneous bleeding in joints and muscles	8 -16
Severe bleeding in joints and muscles, haematoma (swelling caused by collection of blood) in potentially serious situations, blood in the urine	12 – 24

How much do adults require to prevent bleeding?

20 to 40 IU/kg every 2 or 3 days is usually enough.

Children
For children under the age of 6 years, your doctor will recommend the appropriate dose but the usual dose is 17 to 30 IU/kg. This can be given up to 3 times a week for prevention of bleeding.

Previously untreated patients

The safety and efficacy of Optivate in previously untreated patients have not yet been established.

When to inject Optivate
•The medicine should be injected when the first sign of bleeding occurs.
•The injection should be repeated as necessary to stop the bleeding.
•Each individual bleed should be judged on its own severity.
•If you are using this product for the first time, your doctor will supervise you.

Dissolving your medicine before use
Your medicine must **only** be dissolved in the sterilised water provided with the product.

Quantity of Optivate	Volume of Water Supplied
250 IU	2.5 mL
500 IU	5 mL
1000 IU	10 mL

1. Optivate must only be dissolved in the sterilised water provided with the product.
2. Before you remove the "flip-off" top, make sure that the vial of Optivate and the container of water supplied with it are both at **room temperature** (between 20°C and 30°C).
3. Sterilised water for use with Optivate is provided in a glass vial with a stopper.
4. Optivate® is supplied with the amount of sterilised water as shown on the table.

How to Dissolve Optivate
You can dissolve your product using the Transfer Device called Mix2Vial™:
The Mix2Vial™ Transfer Device is provided with your product for needle-free, easy and safe use.

The reconstitution is performed as follows:

	Step 1 •Remove the cap from the product vial and clean the top of the stopper with an alcohol swab. •Repeat this step with the sterile water vial. •Peel back the top of the Transfer Device package but leave the device in the package.
	Step 2 •Place the blue end of the Transfer Device on the water vial and push straight down until the spike penetrates the rubber stopper and snaps into place. •Remove the plastic outer packaging from the Transfer Device and discard it, taking care not to touch the exposed end of the device.
	Step 3 •Turn the water vial upside down with the device still attached. •Place the clear end of the Transfer Device on the product vial and push straight down until the spike penetrates the rubber stopper and snaps into place.
	Step 4 •The sterile water will be pulled into the product vial by the vacuum contained within it. •Gently swirl the vial to make sure the product is thoroughly mixed. Do not shake the vial. •A clear or slightly pearl-like solution should be obtained, usually in about 2 to 2 ½ minutes (5 minutes maximum).
	Step 5 •Separate the empty water vial and blue part from the clear part by unscrewing anti-clockwise. •Draw air into the syringe by pulling the plunger to the required volume of water added. • Connect the syringe to the clear part of the Mix2Vial™. •Push the air in the syringe into the vial.
	Step 6 •Immediately invert the vial of solution which will be drawn into the syringe. •Disconnect the filled syringe from the device. •The product is now ready for administration. Follow the normal safety practices for administration. Use the product immediately after reconstitution, the product must not be stored.

Note: If you have to use more than one vial to make up your required dose, repeat Steps 1 to 6 withdrawing the solution in the vial into the same syringe. The Transfer Device supplied with your product is sterile and cannot be used more than once. When there constitution process is complete dispose of in your 'sharps box'.

Do not use this medicine if:
- the water is **not** pulled into the product vial (this indicates a loss of vacuum in the vial, so the product must **not** be used)
- if at step 6, there are any particles in the syringe, or it if the solution is cloudy, or if a **gel** or **clot** forms (if this happens, please tell Bio Products Laboratory, reporting the batch number printed on the vial).

If you use more Optivate 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 Optivate
Do not use a double dose to make up for a forgotten dose. Inject your normal dose as soon as you remember and then continue dosing as instructed by your doctor or haemophilia nurse.

If you stop using Optivate
Always consult your doctor **before** deciding to stop your treatment.

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

Stop the infusion and tell your doctor immediately or go to the emergency department of your nearest hospital, if you get any of the following symptoms:
• Swelling around the throat
• Flushing
• Hives (nettle rash)
• Feeling lightheaded or dizzy (low blood pressure)
• Rapid heart beat
• Feeling sick or being sick
• Restlessness
• Tightness in the chest or wheezing
• Tingling sensation
These symptoms may worsen into severe shock. The above allergic-type reactions are **very rare** (fewer than 1 patient in every 10,000 patients treated get them).

Other known side effects are:
Adults and Children
Common (more than 1 in every 100 patients treated):
• Headache
• Feeling that everything is moving, spinning round or tilting (vertigo)
• Cough
• Sneezing
• Redness of the skin (rashes) or pain at the place where the medicine was injected
• Other skin rashes
• Swelling in the extremities of the body
• Itching
• Raised temperature (fever)
• Sudden shivering and feeling cold and rapid rise in temperature
• Stiffness in muscles and joints
• Sleepiness, lethargy or feeling unwell

If you get any side effects, talk to your doctor. This includes any side effects not listed in this leaflet.

Reporting of side effects
If you get any side effects, talk to your doctor. 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.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Optivate

- Do not store above 25°C.
- Do not freeze.
- Keep the vial in the outer carton to protect from light.
- 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. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice small bits. Once reconstituted, Optivate must be used within one hour.
- Do not throw away any medicines via wastewater or household waste.Your treatment centre will provide a special container ('sharps box') to dispose any solution that remains, any used syringes, needles and empty containers. These measures will help to protect the environment.

6. Contents of the pack and other information

What Optivate contains

The active substance is human coagulation factor VIII.

The excipients are: sodium chloride, calcium chloride, sodium citrate, polysorbate 20, sodium hydroxide (for pH-adjustment), hydrochloric acid (for pH-adjustment) and trehalose.

This preparation contains human von Willebrand factor (VWF)

What Optivate looks like and contents of the pack
Optivate, in the form of a white or pale yellow powder in quantities of 250 IU (International Units), 500 IU or 1000IU in glass vials. These vials are closed with a synthetic rubber stopper under vacuum, held with a tamper-evident cap.
Optivate should only be reconstituted with sterilised water for injections which is supplied with Optivate in clear glass bottles.
A Transfer Device called Mix2Vial™ is also provided, to enable needle-free, easy and safe reconstitution.

Marketing Authorisation Holder and Manufacturer
Bio Products Laboratory, Dagger Lane, Elstree, Hertfordshire, WD6 3BX, United Kingdom.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Cyprus, Czech Republic, Estonia, Germany, Hungary, Ireland, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, United Kingdom: Optivate

Belgium: Optiwate
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For further information or if you have any questions about the use of this product, please contact BPL via the Marketing Department at the address above or through medinfo@bpl.co.uk.

Bio Products Laboratory,
Dagger Lane,
Elstree,
Hertfordshire,
WD6 38X, UK.