INFORMATION FOR PATIENTS WHO HAVE BEEN PRESCRIBED ELOCTA®▼

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. For reporting within the UK information can be found at www.mhra.gov.uk/yellowcard, and for Republic of Ireland at www.hpra.ie. Side effects should also be reported to Swedish Orphan Biovitrum Ltd at drugsafety@sobi.com

sobi
Pioneer in Rare Diseases

For HCPs to use with their patients who have been prescribed Elocta®.
This booklet is designed to answer questions about Elocta® and how to use it.

CONTENTS

INTRODUCTION TO rFVIIIFc

What is rFVIIIFc and what is it used for?

rFVIIIFc is a medicine used for the treatment and prevention of bleeding in all age groups of patients with haemophilia A (an inherited bleeding disorder caused by factor VIII deficiency).

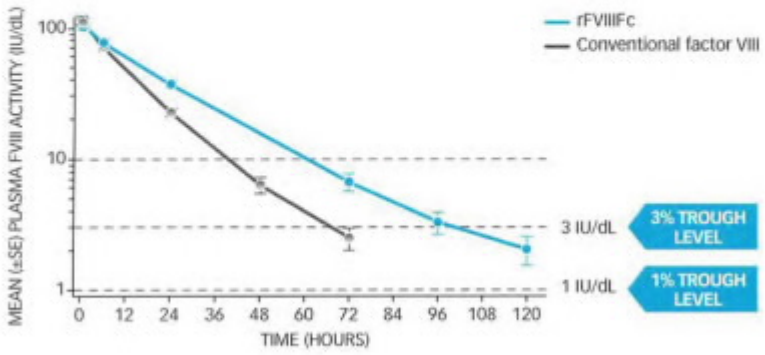
rFVIIIFc contains the active substance efmoroctocog alfa, a recombinant coagulation factor VIII Fc fusion protein. The Fc portion of rFVIIIFc binds to the Fc receptor (FcRn), which is part of a naturally occurring pathway that delays the breakdown of factor VIII in the body by cycling it back into circulation. This means that rFVIIIFc has a longer half-life than conventional factor VIII. Fc fusion has been used for many years in other therapy areas to enable certain medicines to last longer in the body. This is the first time it has been used in haemophilia A. Factor VIII is a protein produced naturally in the body and is necessary for the blood to form clots and stop bleeding.

rFVIIIFc is prepared by recombinant technology without addition of any human- or animal-derived components in the manufacturing process.

What makes rFVIIIFc different?

Through the naturally occurring Fc receptor pathway described above, rFVIIIFc lasts longer in the body than any conventional factor VIII.

rFVIIIFc extends time to trough levels



Adapted from Mahlangu J, et al. Blood. 2014;123:317–25.

USING rFVIIIFc

Treatment with rFVIIIFc will be started by a doctor who is experienced in the care of patients with haemophilia. Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

rFVIIIFc is given as an injection into a vein. Your doctor will calculate your dose of rFVIIIFc (in International Units or "IU") depending on your individual needs for factor VIII replacement therapy and on whether it is used for prevention or treatment of bleeding. Talk to your doctor if you think that your bleeding is not being controlled with the dose you receive.

How often you need an injection will depend on how well rFVIIIFc is working for you. Your doctor will perform appropriate laboratory tests to make sure that you have adequate factor VIII levels in your blood.

If you use more rFVIIIFc than you should

Tell your doctor as soon as possible. You should always use rFVIIIFc exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

If you forget to use rFVIIIFc

Do not take a double dose to make up for a forgotten dose. Take your dose as soon as you remember and then resume your normal dosing schedule. If you are not sure what to do, ask your doctor or pharmacist.

If you stop using rFVIIIFc

Do not stop using rFVIIIFc without consulting your doctor. If you stop using rFVIIIFc you may no longer be protected against bleeding or a current bleed may not stop.

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

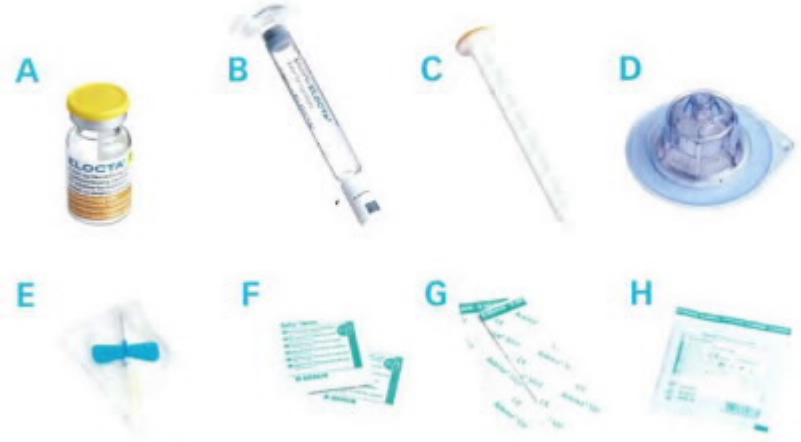
Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original pack in order to protect from light.

Alternatively, rFVIIIFc may be stored at room temperature (up to 30°C) for a single period not exceeding 6 months. Please record on the carton the date that rFVIIIFc is removed from the refrigerator and set at room temperature. After storage at room temperature, the product must not be put back in the refrigerator.

Preparing rFVIIIFc for use

Your pack contains:



A rFVIIIFc vial
B Pre-filled syringe with solvent
C Plunger rod
D Vial adapter
E Butterfly needle injection set
F Sterile swabs
G Plasters
H Gauze pad

Your rFVIIIFc reconstitution kit contains everything you need to prepare rFVIIIFc for injection.

rFVIIIFc must be dissolved using the pre-filled syringe before injection

- First, check the name and dose of the package to make sure it contains the right medicine for you. Check the expiry date on the rFVIIIFc carton. Do not use if the medicine has expired
- If rFVIIIFc has been stored in a fridge, allow the vial (A) and the syringe with solvent (B) to reach room temperature before use. Do not use external heat, such as hot water, a stove or a microwave

If you use more than one vial of rFVIIIFc per injection, each vial should be prepared separately as per the instructions, and the solvent syringe should be removed, leaving the vial adapter in place. A single large luer lock syringe may then be used to draw back the prepared contents of each of the individual vials.

Wash your hands

1

Remove cap from vial and swab top.

2

Remove the backing from the vial adapter package, push the adapter over the vial, and remove the cover.

3

Put the plunger rod into the solvent syringe and turn the plunger rod clockwise until fully secure.

If necessary, after reconstitution rFVIIIFc can be kept at room temperature for up to 6 hours before use. Do not put it back in the fridge.

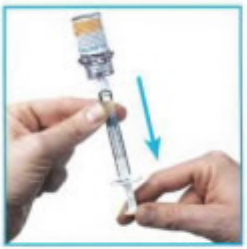
4

Snap the cap off the top of the syringe; insert the tip of the syringe into the adapter opening and secure with a clockwise motion.

5

Slowly depress the plunger rod to inject all of the solvent into the vial; gently swirl the vial until the product is completely dissolved.

6



Turn the vial upside-down and slowly pull the plunger rod to draw the solution into the syringe; gently unscrew the syringe from the vial adapter.

Discard the vial and the adapter.

If you are not going to use the solution immediately, carefully replace the syringe cap. Be careful not to touch the syringe tip or the inside of the cap.

What do I need to know before using rFVIIIFc?

Do not use rFVIIIFc:

- If you are allergic to efmoroctocog alfa or any other ingredients in this medicine

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before using rFVIIIFc as there is a small chance that you may experience an anaphylactic reaction (a severe, sudden allergic reaction) to rFVIIIFc. Signs of allergic reactions may include generalised itching, hives, tightness of the chest, difficulty breathing and low blood pressure. If any of these symptoms occur, stop the injection immediately and contact your doctor
- Talk to your doctor if you think that your bleeding is not being controlled with the dose you receive, as there can be several reasons for this. For example, the formation of antibodies (also known as inhibitors) to factor VIII is a known complication that can occur during the treatment of haemophilia A. The antibodies prevent rFVIIIFc from working properly. This would be checked by your doctor. Do not increase the total dose of rFVIIIFc to control your bleed without talking to your doctor

Catheter-related complications

If you require a central venous access device (CVAD), risk of CVAD-related complications including local infections, presence of bacteria in the blood and catheter site thrombosis should be considered.

Documentation

It is strongly recommended that every time rFVIIIFc is given, the name and batch number of the product are recorded.

Other medicines and rFVIIIFc

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No effects on ability to drive or use of machines have been observed.

rFVIIIFc contains sodium

This medicinal product contains 14 mg sodium per vial after preparation. Talk to your doctor if you are on a controlled sodium diet.

Possible side effects

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

If severe, sudden allergic reactions (anaphylactic reaction) occur, the injection must be stopped immediately. You must contact your doctor immediately if you experience any of the following symptoms of allergic reactions: swelling of the face, rash, generalised itching, hives, tightness of the chest, difficulty breathing, burning and stinging at the injection site, chills, flushing, headache, low blood pressure, general feeling of being unwell, nausea, restlessness and fast heartbeat, feeling dizzy or loss of consciousness.

The following side effects may occur with this medicine.

Uncommon side effects (may affect up to 1 in 100 people)

Headache, dizziness, taste alteration, slow heartbeat, high blood pressure, hot flushes, vascular pain after injection, cough, abdominal pain, rash, joint swelling, muscle pain, back pain, joint pain, general discomfort, chest pain, feeling cold, feeling hot and low blood pressure.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the details noted below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
Dublin 2, Ireland
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

FURTHER INFORMATION

Medical centre details

PERSONAL NOTES

About Sobi™

Sobi™ is committed to improving the lives of people with haemophilia, as well as other rare diseases. Sobi has been working in haemophilia for more than 50 years, and through the work of its predecessor companies, was responsible for the development of the very first factor VIII product, and instrumental in the creation of recombinant factor.

In 2006, Sobi partnered with Biogen™ to work together on the next generation of haemophilia products – resulting in the development of Elocta.

By scanning the QR-code (using a QR-reader app) or typing in the web address found on the Elocta package, you can access instructional films showing how to prepare Elocta before injection, and how to administer Elocta.

QR-readers can be downloaded for free from the App Store or Google Play.

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Document number: NP-1060.
Date of preparation: June 2016.

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ELOCTA®
efmoroctocog alfa
(recombinant human coagulation factor VIII, Fc fusion protein)