

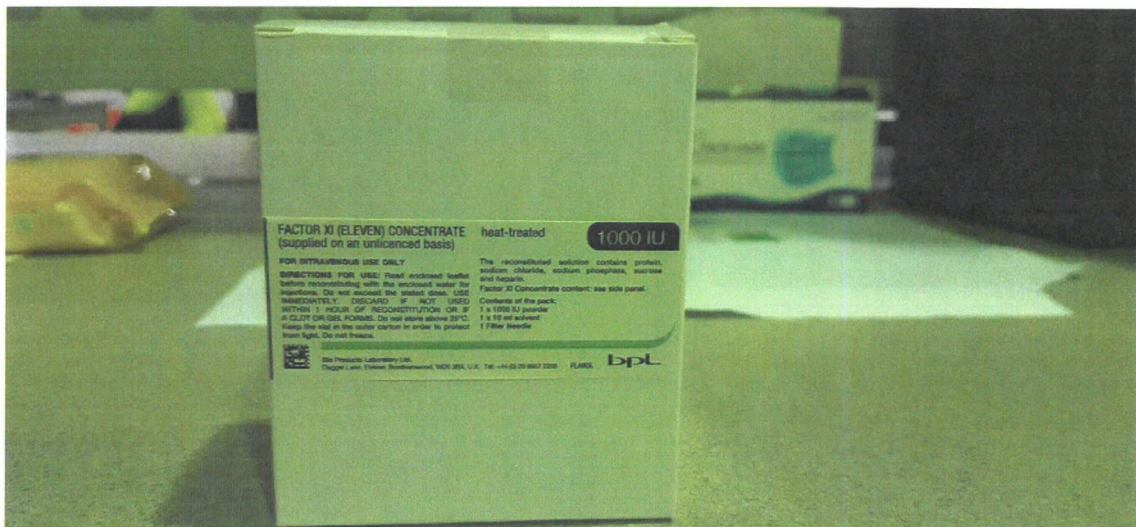
## CHANGE OF PACKAGING NOTIFICATION

### FACTOR XI

WITH IMMEDIATE EFFECT FACTOR XI WILL BE SUPPLIED IN A TWIN PACK – NOT AN INDIVIDUAL VIAL OF PRODUCT AND WFI.

THE COMPONENTS REMAIN EXACTLY AS PREVIOUSLY SUPPLIED.

THE PACKAGING WILL LOOK AS FOLLOWS:



COPIES OF THE LABELS AND PRODUCT INFORMATION LEAFLET ARE ATTACHED.

FOR FURTHER INFORMATION PLEASE CONTACT [ORDERS@BPL.CO.UK](mailto:ORDERS@BPL.CO.UK)

Job No.: **FLAN5L**



100% 95% 50% 5%

Product Name Factor XI named patient label  
 Market UK  
 Component Label  
 No. of Colours 2 (Two)  
 Profile As supplied  
 Dimensions 33 x110 mm  
 Point of Sale Code N/A  
 Pharmacode N/A  
 Datamatrix Code FLAN5L  
 BPL PO No. TBC  
 Asset No. 886  
 Originated on 19/01/2021  
 Originated by Operator 006  
 Originated at ARK  
 Proof Status **P4 / M4**  
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 Amended on 15/02/2022

**TEXT SIZES**

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 Line Spacing 7 pt

**FONTS USED**

Helvetica Neue

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Site Packaging \_\_\_\_\_

BPL Approval L Ambrose

**ARK** PHARMA GRAPHICS  
 Crown House Business Centre  
 Home Gardens, Dartford  
 Kent DA1 1DZ  
 Tel +44(0)1322 424656

Bar prints 100mm @ 100%

**FACTOR XI (ELEVEN) CONCENTRATE**  
(supplied on an unlicensed basis)

heat-treated

**1000 IU**

Factor XI content (IU):

BATCH:

EXPIRY:

Manufacturing license No.:

**FOR INTRAVENOUS USE ONLY**

**DIRECTIONS FOR USE:** Read enclosed leaflet before reconstituting with the enclosed water for injections. Do not exceed the stated dose. USE IMMEDIATELY. DISCARD IF NOT USED WITHIN 1 HOUR OF RECONSTITUTION OR IF A CLOT OR GEL FORMS. Do not store above 25°C. Keep the vial in the outer carton in order to protect from light. Do not freeze.

The reconstituted solution contains protein, sodium chloride, sodium phosphate, sucrose and heparin.

Factor XI Concentrate content: see side panel.

Contents of the pack:  
 1 x 1000 IU powder  
 1 x 10 ml solvent  
 1 Filter Needle



Bio Products Laboratory Ltd.  
 Dogger Lane, Elstree, Borehamwood, WD6 3BX, U.K. Tel: +44 (0) 20 8957 2200

FLAN5L



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FLL14



# Package Leaflet: Information for the User

## Factor XI Concentrate

### human coagulation factor XI

[Supplied on an unlicensed basis]

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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not mentioned in this leaflet. See section 4.

#### In this leaflet:

1. What Factor XI Concentrate is and what it is used for
2. What you need to know before you use Factor XI Concentrate
3. How to use Factor XI Concentrate
4. Possible side effects
5. How to store Factor XI Concentrate
6. Further information

#### 1. What Factor XI Concentrate is and what it is used for

Factor XI Concentrate is a freeze-dried powder for reconstitution with water for injections and is manufactured from blood plasma obtained from screened donors selected from the USA.

Factor XI Concentrate is given by injection into a vein (intravenously) and is used to prevent and treat bleeding in patients either with congenital factor XI deficiency or acquired factor XI inhibitors. Your doctor will explain further why this medicine has been given to you.

#### 2. Before you use Factor XI Concentrate

##### DO NOT USE this medicine if you:

- are **allergic** to factor XI or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Take special care with Factor XI Concentrate if you:

- Suddenly have unusual bruising and/or are feeling very unwell, which may need specialist medical attention.
- Have a risk of blood clotting. Your doctor will discuss this risk with you before treatment.

When injecting, take special care to keep all needles sterile.

If you develop an allergic reaction **tell your doctor immediately** (see section 4 'Possible side effects' for more information).

Your doctor will advise you about any vaccinations you may need as a routine precaution when using Factor XI Concentrate. Your doctor will be extremely careful about using Factor XI Concentrate in new-born babies. Some patients may develop inhibitors (antibodies) to factor XI during treatment with this medicine. This could mean that the treatment will not work properly. Your doctor will check regularly for the development of these antibodies, especially before an operation or during your first course of treatment. Your doctor will probably carry out tests to check the level of factor XI in your blood before and during treatment with this medicine.

##### 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.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for non-enveloped hepatitis A virus. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19 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 infection.

It is strongly recommended that every time you receive a dose of Factor XI Concentrate, the name and batch number of the product are recorded in order to maintain a record of the batches used.

Factor XI named patient PIL UK PIL 1 (One) As Supplied 150 x 196 mm Code N/A N/A FLL14 N/A 887 22/01/2021 Operator 006 ARK **P5 / M5** Operator 006 27/01/2022

Text 8 pt  
g 9 pt

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*Ambrose*

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IICS Tel +44(0)1322 424656

October 2019

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**FLL14**

30% 5%

Factor XI named patient PIL  
UK  
PIL  
1 (One)  
As Supplied  
150 x 196 mm  
Code N/A  
N/A  
FLL14  
N/A  
887  
22/01/2021  
Operator 006  
ARK  
**P5 / M5**  
Operator 006  
27/01/2022

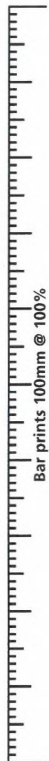
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October 2019



- 4) **Do not use this** medicine if:
  - the water is **not** pulled into the vial (this indicates loss of vacuum in the vial, so the powder must **not** be
  - the dissolved powder and water form a gel or a clot (if this happens please tell Bio Products Laboratory reporting the batch number printed on the vial).
- 5) Continue to swirl gently until the powder is completely dissolved. A clear or slightly opalescent solution should be obtained within 10 minutes.
- 6) If you have to use more than one vial to make up your dose, you need to draw up the solution in a syringe for your injection, but you must use a new sterile filter needle to draw the contents of each into the plastic syringe.
- 7) **Do not use** solutions which are cloudy or have bits in them.

**Injecting the medicine**

After the medicine is dissolved:

- Clean the stopper, with a spirit swab.
- Draw the medicine into a plastic, disposable syringe through a sterile filter needle (this will remove any 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.

**Remember:**

- The solution must **not** be stored after reconstitution.
- You **must** finish injecting the dose into a vein within **one hour** of dissolving the medicine.
- The solution must **not** be added to any other fluids, blood or any other medicine.
- You should only use the water for injections supplied with this medicine to make up the solution, but must never inject the water on its own, without the powder.

**If you use more Factor XI Concentrate than you should**

If you think you are being given too much, stop the injection and tell your doctor. If you know you have used too much tell your doctor.

**If you forget to use Factor XI Concentrate**

Tell your doctor.

**If you stop using Factor XI Concentrate**

Always consult your doctor **before** deciding to stop your treatment.

**4. Possible side effects**

There are reports of side-effects due to blood clots within a few days of factor XI concentrate being given to elderly patients with other risk factors. Your doctor will advise you about these risks and monitor you closely. As with all blood products, occasional side effects may include skin rash, flushing, nausea and headache which are controlled by slowing or stopping the infusion. In rare cases, allergic reactions or a rise in temperature may be observed. If you get any of these contact your doctor. The treatment for these effects depends on the nature and severity of the side effect.

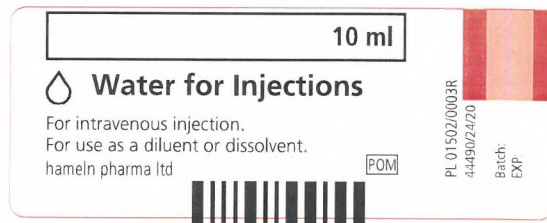
You may develop neutralising antibodies (inhibitors) to factor XI, which can make the medicine less effective. Your doctor will monitor you for these.

In addition to the above, Clinical experience has been associated with the following undesirable effects:

- |                            |                             |
|----------------------------|-----------------------------|
| • heart attack             | • difficulty in breathing   |
| • dizziness                | • heart failure             |
| • wheezy breathing         | • feeling lightheaded       |
| • poor circulation (shock) | • fluid on the lungs        |
| • feeling cold             | • low blood pressure        |
| • chest pain               | • tiredness                 |
| • rapid or slow heart beat | • coughing up blood         |
| • feeling unwell           | • irregular heart beat      |
| • increased sweating       | • pain in back or limbs     |
| • swelling in legs         | • redness at injection site |
| • tendon disorders         | • cramps                    |

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this list. You can also report side effects directly via the email address [adr@bpl.co.uk](mailto:adr@bpl.co.uk). By reporting side effects you can help provide more information on the safety of this medicine.

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Date last revised:	08/06/2020
Last revised by:	J.Jones
Customer	hameln pharma ltd
Country	UK
Language:	English
Product:	WFI
Component:	Label 10ml (Siegfried-HamelN)
Dimensions:	60 x 28 mm
Software:	Adobe Illustrator CC
Font(s):	Frutiger light, bold
Colour(s):	Schwarz
Signature:	