CSL Behring

PATIENT INFORMATION LEAFLET

FIBROGAMMIN® 250/1250 IU
Powder and solvent for injection or infusion

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or your haemophilia nurse. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

IN THIS LEAFLET:

1. WHAT FIBROGAMMIN IS AND WHAT IT IS USED FOR

Fibrogammin (Factor XIII) is a product made from human plasma (this is the liquid part of the blood). It is used to prevent or stop the bleeding that you might get because of a lack of factor XIII in your blood, a condition that you have had from birth. Factor XIII is needed for the formation of blood clots which help bleeding to stop and helps slow healing wounds to heal more quickly.

2. BEFORE YOU USE FIBROGAMMIN

Do not use Fibrogammin

- If you are allergic to any of the ingredients (see section 6). If you are unsure about this, ask your doctor.

Take special care with Fibrogammin

- If you experience any signs of an allergic reaction to Fibrogammin (for example a rash, tight chest, wheezing or feeling dizzy), stop injecting the product **immediately** and contact your doctor.
- You should visit your doctor or haemophilia treatment centre regularly to ensure that your dose is correct. The doctor may wish to carry out some tests to make sure that you are getting the right amount.
- If your bleeding is not being controlled with Fibrogammin, tell your doctor **immediately**. You may have developed an inhibitor (an antibody which can cancel out the effects of factor XIII) and your doctor may wish to carry out more tests to confirm this.

Note: After repeated treatment, patients should be carefully monitored for the development of inhibitors to Factor XIII by appropriate clinical observation and laboratory tests.

- If you have ever had a blood clot (thrombosis), you should ask your doctor for advice. See section 4 for signs of a thrombosis.

Taking or using other medicines
There are no medicines that are known to react with Fibrogammin. However, if you are taking another medicine and are concerned, please ask your doctor or haemophilia nurse.

Fibrogammin must not be mixed with other medicinal products except those mentioned in section 3 and should be administered by a separate infusion line.

Pregnancy and breast-feeding
If you are pregnant or planning a family soon, or if you are breast-feeding, ask your doctor for advice before using this product.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

Important information about some of the ingredients of Fibrogammin
Fibrogammin contains up to 189 mmol/L sodium (17/87 mg per 250/1250 IU vial). Please take this into account if you are on a sodium (salt) controlled diet as you may need to cut down on the salt in your diet.

Fibrogammin contains 24/120 mg glucose per 250/1250 IU vial. Please take this into account if you have diabetes.

Important safety information related to infections
When medicines are made from human blood, steps are taken to prevent virus infections being passed on to the patient.
These steps include:
- Careful selection of blood donors to ensure that those at risk of carrying infections are excluded,
- Testing of each donation for signs of infection,
- Steps in the manufacture to inactivate or remove viruses.

The measures taken are considered effective for enveloped viruses such as HIV, hepatitis B and C and for the non-enveloped viruses hepatitis A and parvovirus B19.

However, there is still a small chance of an infection being passed on to the patient. This may include a new virus or other type of infection.

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

Every time you receive a dose of Fibrogammin, it is important to note the name and batch number of the medicine (shown on the carton) in order to maintain a record of the batches used.

3. HOW TO USE FIBROGAMMIN

The amount of factor XIII you need will depend on several factors, such as your weight, the severity of your condition, the site and severity of bleeding or the need to prevent bleeding during an operation or investigation.

Fibrogammin is given by injection or infusion into a vein.

If you have been prescribed Fibrogammin to use at home, your doctor or haemophilia centre nurse will make sure that you are shown how to inject it and how much to use.

If you are in any doubt about injecting Fibrogammin, go back to your doctor or haemophilia centre for more advice and training before attempting to treat yourself.

Follow the directions given to you by your doctor or haemophilia nurse. You can also use the directions given below as a guide.

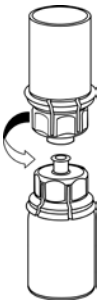
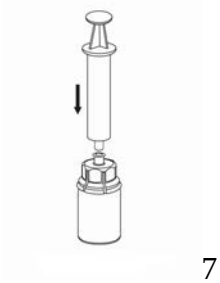
Directions for preparing and administering Fibrogammin
Wash your hands thoroughly using soap and warm water.

Warm the Fibrogammin powder and liquid (Water for Injections) vials to room temperature without opening either container. You can do this by leaving them to stand at room temperature for about an hour after taking them out of the fridge or if you need them quickly, hold them in your hands for a few minutes.

DO NOT expose the containers to direct heat or stand them on a radiator.
They must not be heated above body temperature (37º C).

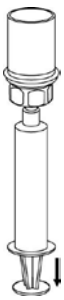
Ensure that product and solvent vial flip caps are removed and the stoppers are treated with an antiseptic solution and allowed to dry, prior to opening the Mix2Vial package.

 1	1. Open the Mix2Vial package by peeling off the lid. Do **not** remove the Mix2Vial from the blister package!
 2	2. Place the **solvent vial** on an even, clean surface and hold the vial tight. Take the Mix2Vial together with the blister package and push the spike of the **blue** adapter end **straight down** through the solvent vial stopper.
 3	3. Carefully remove the blister package from the Mix2Vial set by holding at the rim and pulling **vertically** upwards. Make sure that you only pull away the blister package and not the Mix2Vial set.

 4	4. Place the **product vial** on an even and firm surface. Invert the solvent vial with the Mix2Vial set attached and push the spike of the **transparent** adapter end **straight down** through the product vial stopper. The solvent will automatically flow into the product vial.
 5	5. With one hand grasp the product-side of the Mix2Vial set and with the other hand, grasp the solvent-side and unscrew the set counter-clockwise carefully into two pieces. Discard the solvent vial with the blue Mix2Vial adapter attached.
 6	6. Gently swirl the product vial with the transparent adapter attached until the substance is fully dissolved. Do not shake.
 7	7. Draw air into an empty, sterile syringe. While the product vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting by screwing clockwise. Inject air into the product vial.

Once you have made up the solution according to the instructions above, it should be used immediately in order to avoid microbial contamination. Do not freeze the reconstituted solution.

Withdrawal and application

 8	8. While keeping the syringe plunger pressed, turn the system upside down and draw the solution into the syringe by pulling the plunger back slowly.

 9	9. Now that the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the transparent Mix2Vial adapter from the syringe by unscrewing counter-clockwise.

The solution should be clear or slightly opalescent. After filtering/withdrawal the reconstituted product should be inspected visually for particulate matter and discoloration prior to administration. Do not use solutions which are cloudy or contain residues (deposits/particles).

Care should be taken that no blood enters the syringe filled with product, as there is a risk that the blood could coagulate in the syringe and fibrin clots could therefore be administered to the patient.

In case more than one vial of Fibrogammin is required, it is possible to pool several vials of Fibrogammin for a single infusion via a commercially available infusion device.

The Fibrogammin solution must not be diluted.

The reconstituted solution should be administered into a separate injection / infusion line (provided with the product) by slow intravenous injection, at a rate note exceeding 4 ml per minute.

Any unused solution should be left in the vial or syringe. Dispose of all vials, needles, syringes and antiseptic swabs as you have been told. Do not throw them away with your household rubbish.

If you use more Fibrogammin than you should
No cases of overdose have been reported.

If you forget to use Fibrogammin
Inject your normal dose as soon as you remember and then continue as instructed by your doctor or haemophilia nurse.

4. POSSIBLE SIDE EFFECTS

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

Rare side effects (affect less than 1 in 1,000 people):

- Rise in temperature
- Rash, itchy swellings on the skin (hives)
- Low blood pressure which could make you feel faint or dizzy
- Difficulty breathing

Fibrogammin could increase your risk of a thrombosis.

Symptoms of a thrombosis include:

- Unusual pain or swelling in your legs
- Sudden sharp pain in your chest
- Sudden difficulty breathing
- An unusual, severe or long-lasting headache
- Dizziness or fainting

If you have any of these symptoms, **stop your injection immediately** and contact your doctor.

If you notice that your Fibrogammin is less effective than usual, contact your doctor or haemophilia centre immediately.

Reporting of side effects
If you get any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the UK Yellow Card Scheme. Website: www.mhra.gov.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. STORING FIBROGAMMIN

Store in a fridge at 2 ºC to 8 ºC, in the original packaging. Do not freeze.

Keep out of the sight and reach of children.

Do not use Fibrogammin after the expiry date on the carton.

6. FURTHER INFORMATION

What Fibrogammin contains

The active substance is:

- 250/1250 International Units (IU) human plasma coagulation factor XIII

Other ingredients are:

- human albumin
- glucose monohydrate
- sodium chloride
- traces of sodium hydroxide may be present, (used for pH adjustment).

Presentations

Pack with 250 IU
1 vial with powder
1 vial with 4 ml Water for Injections
1 filter transfer device 20/20

Administration set (inner box):
1 disposable 5 ml syringe
1 venipuncture set
2 alcohol swabs
1 non-sterile plaster

Pack with 1250 IU
1 vial with powder
1 vial with 20 ml Water for Injections
1 filter transfer device 20/20 (Mix2Vial)

Administration set (inner box):
1 disposable 20 ml syringe
1 venipuncture set
2 alcohol swabs
1 non-sterile plaster

Bottles of product and liquid may appear partly empty but this is normal and does not mean that there is the wrong amount of powder or solution.

Marketing Authorisation Holder and Manufacturer
CSL Behring GmbH, Emil-von-Behring-Strasse 76, 35041 Marburg, Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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