MonoFIX®-VF

Human coagulation factor IX.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MonoFIX®-VF. It does not contain complete information about MonoFIX®-VF. It does not take the place of talking to your doctor.

If you have any concerns about using this medicine, please talk to your doctor. Follow your doctor's advice, even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your haemophilia treatment centre if there is any new information about this medicine that you should know since you were last treated.

What MonoFIX®-VF is used for

MonoFIX®-VF contains purified and concentrated factor IX, a protein which is essential for normal blood clotting. MonoFIX®-VF is used in patients with haemophilia B or Christmas disease, a bleeding disorder, in which there are reduced levels of the clotting factor. Also, it is available for use in surgery.

Individuals with factor IX levels lower than normal have difficulty in forming blood clots, with these clots often taking longer to be made than normal. Sometimes the individual may bleed unexpectedly into their joints, muscles or internal organs.

Ask your haemophilia treatment centre if you have any questions about why MonoFIX®-VF has been prescribed for you.

Before you are given MonoFIX®-VF

Tell your doctor if you:

- have allergies to any medicines
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores.
- have any other medical conditions
- are pregnant or breast-feeding
- become pregnant during your treatment.

If you want further information, consult your doctor or haemophilia treatment centre.

About blood products

MonoFIX®-VF is manufactured from human plasma (the liquid component of blood) collected by Australian Red Cross Lifeblood. When products are made from human blood and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or parvovirus B19 and theoretically the Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents some of which may not yet have been discovered.

To reduce the risk of this happening extra steps are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to remove and kill viruses. This special treatment is considered

effective against certain viruses known as enveloped viruses (such as HIV and hepatitis B and C), and also the non-enveloped virus, hepatitis A. They are also known to have some effect on the removal of the non-enveloped virus, parvovirus B19. Despite these measures, the risk of viral and other agent's infectivity cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this product with your doctor.

How to use MonoFIX®-VF

The dosage and administration of MonoFIX®-VF must be carefully controlled. Your doctor will be responsible for determining what dose is appropriate to your condition.

MonoFIX®-VF will usually be given in a hospital. Should your doctor decide that treatment at home is appropriate, your haemophilia treatment centre will provide detailed instructions on how to use MonoFIX®-VF.

The following procedures are given as a guide only.

Preparing MonoFIX®-VF for administration

Allow the vials of MonoFIX®-VF and Water for Injections to reach room temperature prior to use, which may take one hour. Do not warm the Water for Injections in hot water. You will need one 5 mL Water for Injections for each 500 IU (100 IU/mL) vial of MonoFIX®-VF, or one 10 mL Water for Injections for each 500 IU (50 IU/mL) and 1000 IU vial of MonoFIX®-VF.

1. Remove jewellery, watches, rings, etc.
2. Wash hands with soap and water, dry with a clean towel.
3. Select an appropriate work area with good lighting and a surface which can be cleaned (such as a kitchen table).
4. Using a clean cloth or paper towel, clean the preparation area with methylated spirits.
5. Gather the equipment to be used.

Equipment

- One carton of MonoFIX®-VF containing:
  - one vial of MonoFIX®-VF
  - one vial of Water for Injections
  - one Mix2Vial™ filter transfer set.

Check the expiry date on each item. Do not use if expired.

- two alcohol wipes
- sharps container
- waste container for discarding biological material
- plastic syringe(s)
- adhesive tape
- cotton balls
- intravenous injection set
- gloves.

The injection is best prepared by following each of the steps outlined in turn.

1. Wash hands with soap and water, dry with a clean towel.
2. Ensure MonoFIX®-VF and the Water for Injections are at room temperature.
3. Remove protective caps from both the MonoFIX®-VF and Water for Injections vials.
4. Wipe the rubber stoppers of both the MonoFIX®-VF and Water for Injections vials with the alcohol wipes and allow to dry for two minutes. Do not leave alcohol wipes resting on the stoppers. Do not touch the rubber stoppers with your fingers.

5. Open the lid of the Mix2Vial™ packaging. **If the seal of the lid is not intact or you have any other concerns about the integrity of the Mix2Vial™, do not use it but return it to your haemophilia treatment centre or Australian Red Cross Lifeblood.** Place the Water for Injections vial on a level surface and hold the vial firmly. Take the Mix2Vial™ together with the outer package, invert it and push the blue plastic cannula of the Mix2Vial™ firmly through the rubber stopper of the Water for Injections vial, see **Figure 1** (5 mL Water for Injections is provided for 500 IU (100 IU/mL) vial and 10 mL Water for Injections is provided for 500 IU (50 IU/mL) vial and 1000 IU vial).

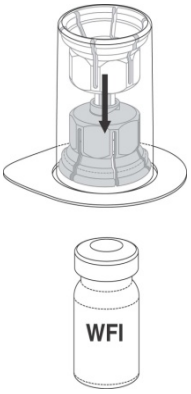

Figure 1

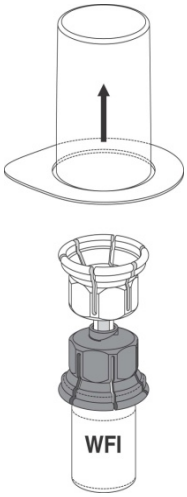

Figure 2

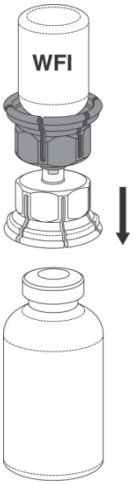

Figure 3

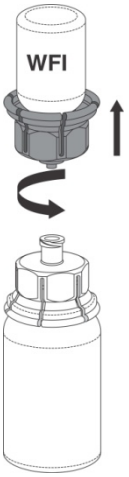

Figure 4

WFI = Water for Injections

6. While holding onto the vial of Water for Injections, carefully remove the outer package from the Mix2Vial™, being careful to leave the Mix2Vial™ firmly attached to the vial of Water for Injections, see **Figure 2**. Make sure that you only remove the outer package and not the Mix2Vial™.

7. With the MonoFIX®-VF vial held firmly on a level surface, invert the Water for Injections vial with the Mix2Vial™ attached and push the transparent plastic cannula end of the Mix2Vial™ firmly through the stopper of the MonoFIX®-VF vial, see **Figure 3**. The water will be drawn into the vial by the vacuum contained within the MonoFIX®-VF vial. **If water is not drawn into the vial, it means that there is no vacuum in the**

vial and the seal may be faulty. Do not use the product but return it to your haemophilia treatment centre or Australian Red Cross Lifeblood.

Note: The Mix2Vial™ is intended to filter the contents of a single vial of MonoFIX®-VF only. If multiple vials of MonoFIX®-VF are to be given, a separate Mix2Vial™ must be used for each vial.

8. With the Water for Injections and MonoFIX®-VF vials still attached to the Mix2Vial™, gently swirl (do not shake) the MonoFIX®-VF vial until all of the product is dissolved. Ensure the contents of the vial are completely dissolved. If a clot or gel forms do not use the product but return it to your haemophilia treatment centre or Australian Red Cross Lifeblood.
9. Once the contents of the MonoFIX®-VF vial are completely dissolved, firmly hold both the transparent and blue parts of the Mix2Vial™. Unscrew the Mix2Vial™ into two separate pieces, see **Figure 4**. Discard the empty Water for Injections vial with the blue part of the Mix2Vial™ still attached into an appropriate waste container.
10. While the MonoFIX®-VF vial is upright, attach a plastic disposable syringe to the transparent part of the Mix2Vial™. Invert the system and draw the MonoFIX®-VF into the syringe by pulling the plunger back slowly.
11. Once the MonoFIX®-VF has been transferred into the syringe, firmly hold the barrel of the syringe (keeping the syringe plunger facing down) and detach the Mix2Vial™ from the syringe. Do not use the Mix2Vial™ for injection.

    Note: One large syringe may be used to withdraw MonoFIX®-VF from multiple vials.
12. Discard the empty vial of MonoFIX®-VF with the transparent part of the Mix2Vial™ attached, into an appropriate waste container.

Use MonoFIX®-VF as soon as you can after preparation (for use in one patient on one occasion only). The solution must not be stored and the infusion should be completed within 3 hours. Any unused portion remaining in the vial must be discarded appropriately.

Do not refrigerate MonoFIX®-VF once it has been prepared.

Injection administration procedure guidelines

The injection is best given by following each of the steps outlined in turn.

Should any of the symptoms listed under 'Side effects' develop, stop the infusion immediately and contact your haemophilia treatment centre.

1. Apply tourniquet. Select injection site.
2. Wash hands with soap and water, dry with a clean towel.
3. Cleanse the skin area with an alcohol wipe, allow to dry.
4. Put on gloves.
5. Insert intravenous needle into vein.
6. Secure needle with adhesive tape.
7. Attach the syringe containing MonoFIX®-VF to the intravenous needle.
8. Draw blood back into the syringe, to check the needle is in the vein, and to remove air from the intravenous line.
9. Remove tourniquet.

10. Administer the MonoFIX®-VF solution slowly (approximately 3 mL per minute or as tolerated).

Slow the rate of infusion or stop the infusion if any sign of unwanted effects is recognised.

1. Carefully remove adhesive tape.
2. Carefully remove the intravenous needle with syringe attached and place directly into the sharps container.
3. Apply pressure to the injection site using a cotton ball for one to two minutes. Apply dressing if necessary.
4. Discard all used sharps into the sharps container, and dispose of the other used equipment appropriately.
5. Wash hands with soap and water, dry with a clean towel.

Side effects

Along with their intended effects, medicines may cause some unwanted effects, which can sometimes be serious. Furthermore, individual patients may react differently to the same dose of the same medicine. This applies to MonoFIX®-VF. A constituent of this formulation (heparin sodium) may lead to maternal bleeding episodes, thereby causing an increased incidence of foetal loss and prematurity.

Although severe reactions after MonoFIX®-VF injection are rare, high doses of factor IX may on rare occasions cause heart attacks and blood clots.

Stop using this product immediately and contact your haemophilia treatment centre if any of the following side effects occur:

- fever
- chills
- dizziness or nausea
- itching
- rash
- tightness of the chest
- wheezing.

Other side effects include:

- injection site reactions
- cold clammy skin
- taste disturbances.

Flare and anaemia have also been reported during a Clinical Trial with MonoFIX® (CSL's human factor IX product prior to the introduction of a virus filtration step).

Contact your doctor immediately if you experience any of these symptoms at any time:

- fever
- loss of appetite
- extreme tiredness
- abdominal pain
- jaundice (yellow skin and eyes)
- dark urine
- joint pains
- skin rashes.

Ask your haemophilia treatment centre if you need more information.

Overdose

Overdosage may enhance the risk of heart attacks and blood clots. If you have questions, consult your haemophilia treatment centre.

Storing MonoFIX®-VF

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

MonoFIX®-VF must not be used after the expiry date printed on the label.

Further information

This is not all the information that is available on MonoFIX®-VF. If you have any more questions or are not sure about anything, ask your haemophilia treatment centre.

Product description

What it looks like

MonoFIX®-VF is a white powder contained in a glass vial. MonoFIX®-VF is registered in three presentations. Each pack size contains:

1. 500 IU vial of MonoFIX®-VF, 10 mL vial of Water for Injections (for a factor IX concentration of 50 IU per mL) and a special filter transfer set called a Mix2Vial™.
2. 500 IU vial of MonoFIX®-VF, 5 mL vial of Water for Injections (for a factor IX concentration of 100 IU per mL) and a special filter transfer set called a Mix2Vial™.
3. 1000 IU vial of MonoFIX®-VF, 10 mL vial of Water for Injections, (for a factor IX concentration of 100 IU per mL) and a special filter transfer set called a Mix2Vial™.

Ingredients

MonoFIX®-VF contains 500 IU or 1000 IU of factor IX as the active ingredient. The 500 IU (50 IU/mL) contains 10 IU/mL of heparin sodium and 1.25 IU/mL of antithrombin III. The 500 IU (100 IU/mL) and 1000 IU contain 20 IU/mL of heparin sodium and 2.5 IU/mL of antithrombin III. Other ingredients include human plasma proteins, sodium phosphate, sodium citrate and sodium chloride.

Manufacturer

MonoFIX®-VF is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189–209 Camp Road
Broadmeadows VIC 3047
Australia

Distributor

Australian Red Cross Lifeblood

Date of revision

April 2020

Australian Register Numbers
500 IU (50 IU/mL): AUST R 66066
500 IU (100 IU/mL): AUST R 101710
1000 IU: AUST R 101711

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