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Grifols UK has prepared this training manual as guidance for homecare patients and their family members or others who will assist you with an infusion of Flebogamma® DIF. Please remember that this manual should only be used in conjunction with Flebogamma® DIF infusions. If you are unsure of how to proceed with any part of your infusion, please contact either your doctor or your referral centre.

Flebogamma® DIF is available in two solution strengths: 5% and 10%. It is also available in various vial (or bottle) sizes: 10ml, 50 ml, 100 ml, 200 ml and 400 ml. These different bottle sizes allow you the flexibility of using one or a combination of bottles to give you the correct dose for your weight, without having to discard any product. More information on how to change the bottle during your infusion can be found on page 22.

In the photographs in this brochure we have used a 50 ml bottles containing 5g of Flebogamma® DIF, i.e. a 10% solution.
Homecare with Grifols UK

Grifols UK offers a comprehensive homecare service, which ensures the delivery of our therapies, along with all the necessary accessories, directly to an address of your choice. This service is provided free of charge.

Co-ordination

• Grifols Homecare has a dedicated team who oversee all aspects of your Homecare service. Contact with patients is either by telephone or e-mail.

Delivery

• Grifols Homecare is able to offer a flexible delivery service to suit you.

• Grifols Homecare utilises its own temperature controlled van and dedicated drivers. This enables control of the service to ensure deliveries arrive when required.

• The temperature controlled van is unmarked and patients will normally see the same delivery driver each time.

• We aim to deliver within a 2 hour time slot.
Provision of Accessories

• A full range of infusion accessories is supplied with each delivery of your therapy if required.

Collection Service

• Grifols Homecare will collect clinical waste bins and dispose of them safely.

Record Keeping

• Grifols Homecare believes that comprehensive record keeping is essential. Records are maintained of all deliveries. These include the batch information relating to the therapeutic product supplied to you.

• All records are strictly confidential; your privacy is of utmost importance to Grifols UK.

• Detailed records, including contact names, addresses and telephone numbers for consultants and nursing staff are up dated regularly, thus ensuring accurate and timely deliveries.
Flebogamma® DIF

What is Flebogamma® DIF and how is it given?

Flebogamma® DIF is one of the group of medicines called intravenous immunoglobulins. These are used to treat conditions where the body’s defence system against disease is not working properly.

Flebogamma® DIF is a clear solution of human antibodies (also called immunoglobulins) in a 5% sorbitol solution which stabilises the antibodies during storage. The antibodies are extracted and purified from human plasma.

What is Flebogamma® DIF used for?

Flebogamma® DIF is used to raise antibody levels in your blood. A lower than normal level of antibodies in your blood results from the incorrect functioning of your body’s defence (immune) system and is called an immunodeficiency. The low levels of antibodies may be inherited or may have developed as you have grown older (primary immunodeficiency). Other medical conditions can also reduce the level of antibodies in your blood (secondary immunodeficiency). Raising antibody levels by regular infusions of Flebogamma® DIF will help your body fight off infections.
Flebogamma® DIF is also used to treat a condition called idiopathic thrombocytopenic purpura (ITP), where the number of platelets in your bloodstream is greatly reduced. Platelets form an important part of the clotting process and a reduction in their numbers may cause unwanted bleeding and bruising. Infusion of Flebogamma® DIF results in an increase in the number of platelets, and an improvement in your condition.

**How is Flebogamma® DIF given?**

Flebogamma® DIF is given by infusion into your veins (intravenous administration).

Flebogamma® DIF may be self administered only after you have been fully trained by hospital staff. You must **never** self administer Flebogamma® DIF alone. Always have a qualified person present.

It is important that the infusion is given slowly at first. If it is given too quickly, side effects such as those listed on page 30 may occur. If side effects do occur then the speed of the infusion must be reduced or the infusion should be stopped completely.
Clean technique

‘Clean’ technique must be used when inserting the infusion needle (venepuncture) and administering intravenous immunoglobulin (IVIG) products. It is vital that the manner in which the venepuncture/infusion is performed minimises the risk of introducing an infection. Clean technique essentially involves not contaminating any sterilised material (i.e. venepuncture needles). Serious infection may result if appropriate precautions are not followed. Mastering the clean technique is therefore, an essential part of the IVIG infusion.

The following general principles apply to clean technique:

- Always select a comfortable, well-lit area for the infusion, such as a desk, kitchen table, or countertop. Clear the area of any unnecessary items. Clean the area with a damp sponge or washcloth and wipe it dry. Disinfectant wipes should be used for a thorough cleaning.

- Do not open sterile needle and other packages until you are ready to use them. If a needle is accidentally touched or contaminated, discard it and use a new sterile one.

- Remove the plastic cap from the Flebogamma® DIF bottle to expose the rubber stopper just prior to use.

- Clean the venepuncture site with alcohol swab prior to inserting the needle, in order to reduce the risk of bacterial contamination.

“Use a disinfectant wipe to clean thoroughly the area you have chosen to for the infusion”
Clean technique

• Select a clean, comfortable surface for the infusion taking care to clean and wipe it dry.

• Use the sterile drape provided.

• Swab the venepuncture site with alcohol swab just prior to infusion to reduce the risk of bacterial contamination.

• Keep needles and Giving Set tips covered until ready for use.

• Never use items that may have been accidentally contaminated.

• Discard used/contaminated items in the sharps bin provided.

• Keep note of the batch number in your infusion log using the peel off bottle labels.

Key points to remember
Items required for venepuncture and infusion

The following items should always be available before starting an infusion of Flebogamma® DIF

- Flebogamma® DIF
- Drip stand
- Infusion (Giving) set
- Disinfectant wipes
- Sterile drape
- Tourniquet
- Surgical tape
- Butterfly (winged) needle
- Scissor clamp
- Gauze swabs
- Alcohol swabs
- Sharps bin
- Diary or infusion log*
- Watch*
- Pen*

*Not provided
Preparing for the infusion

1. Gather all the materials you will need for the infusion process (a)

2. Make the following checks:

   • You have the correct number of bottles of Flebogamma® DIF and they are the right size, i.e. the correct dose. (More appropriately this should be checked once you have received your delivery).

   • Check seal and ensure solution is clear. Do not use any bottles where the liquid appears cloudy or if there is a deposit in the bottom of the bottle. (b)

   • Check the label. Flebogamma® DIF must be used before the expiry date. There is also a batch number for you to record. Flebogamma® DIF has special peel off labels to help with this – peel the batch number label from the product and stick the label in your diary. (c)

   • Flebogamma® DIF can be stored up to 30°C. However, should it be stored in a fridge then it must be allowed to warm to room temperature before use.
Preparing for the infusion  Preparation of the area

3. Wash and dry your hands. (d)

4. Clean the area and wipe with a disinfectant wipe. (e)

5. Use a sterile drape to cover the work surface. (f)
Preparing for the infusion
Preparation of the Giving Set

1. Take Giving Set out of packaging and move the roller clamp to the required position. Ensure roller clamp is closed and loosen connection on Giving Set.

2. Remove the plastic top from the Flebogamma® DIF bottle.

3. Remove the cover from the Giving Set spike and push it through the centre of the rubber stopper.

4. Invert the Flebogamma® DIF bottle and using the label hanger, hook onto the drip stand.
Preparing for the infusion  Preparation of the Giving Set

5. Open tab to allow liquid to flow.

6. With the roller clamp still closed, squeeze the drip chamber, then release slowly to allow the liquid to half fill the chamber.

Remember: do not interrupt any part of this procedure—continue once started.

7. Slowly open the roller clamp to allow Flebogamma® DIF to fill the Giving Set and force the air out of the tubing, thus filling the whole of the line with liquid.

8. Close the clamp. (If there are any air bubbles tap the line to make the bubbles rise).
Preparing for Venepuncture

1. Arrange the required supplies and ensure forearms and hands are warm. Cut three strips of surgical tape and place them conveniently.

2. Wash and dry your hands.

3. Open the packets for the alcohol swab, gauze swab and butterfly needle.
4. Check that the stopper on the butterfly needle is loose.

5. Put the tourniquet about 3 to 5 inches (7-12 cm) above your intended site. Tighten it enough to cause your veins to swell. Do not over tighten or leave tourniquet on for longer than 5 minutes.
Venepuncture

1. Choose a prominent vein and clean with an alcohol swab.

2. Hold the plastic wings of the butterfly needle and ensure the needle bevel is upward. Enter the skin directly over the vein with the tip of the needle toward your upper arm. The needle should be at about a 25 to 30 degree angle to the skin for arm venepuncture and 15 to 20 degrees for hand venepuncture. After penetrating the skin with the needle tip, decrease the needle angle to 10 degrees from the horizontal. Then advance the needle until you see blood in the tubing.

   **Do not panic** if you miss a vein – if possible place a clean warm towel over the site before trying again. (If you continue to experience problems finding your vein contact your local immunology team for further advice).

3. Once you see blood starting to come into the tubing, decrease the angle of the needle until it is almost flat against the skin. Then advance the needle just a little further to be sure it is properly positioned.
Venepuncture

4. Now open out the wings of the butterfly needle and use surgical tape to secure them to your skin.

5. Loosen the stopper from the tubing of the butterfly needle and allow blood to flow to the end of the tube. Clamp the tube with the scissor clamp.

6. Remove the tourniquet. Then remove the stopper from the butterfly needle tubing.
The infusion How to start the infusion

1. Remove the cover from the Giving Set and connect to the end of the butterfly needle tubing.

2. Now remove the scissor clamp

3. Open the roller clamp on the Giving Set and adjust your drop rate. (See infusion rate section).
4. In some circumstances an air inlet needle may be required to achieve the correct flow rate.

5. Using surgical tape, secure the Giving Set tubing.
The infusion
How to change the bottle

1. Close the roller clamp on the Giving Set if drip chamber is empty. If the drip chamber is full, do not clamp.

2. Hang next bottle. Remove the Giving Set spike from the empty bottle and insert it into the next Flebogamma® DIF bottle which is on the hanger. Do not touch the spike itself and ensure no air gets into the infusion set tubing. Remember to open the red tab and change the air inlet needle, if one has been used.

3. Open the roller clamp and continue your infusion.
The infusion

How to complete the infusion

1. The infusion is complete when the drip chamber has emptied. After all the Flebogamma® DIF has been infused, close the Giving Set roller clamp.

2. Remove the surgical tape and your partner can place a gauze swab over the venepuncture site.

3. Now remove the needle in one swift motion.
4. Maintain firm pressure on the site for 3 to 5 minutes.

5. Once bleeding has stopped, you can apply a gauze swab if required.

6. Now dispose of the used materials carefully. Needles and giving sets should be placed in the sharps bin. (Do not keep your sharps bin for longer than 6 months.) Never attempt to retrieve any items from the sharps bin. The rest of the infusion items that have been used can be thrown away as normal rubbish, but for safety, double wrap the contents first.
7. Your work area should then be cleaned and your hands washed again.

8. Finally, record any additional information in your diary. (Remember, you will have already stuck the label with the batch number into your diary prior to starting the infusion - see page 12).
Problems that may occur during the infusion

• If you experience slight discomfort at the site of infusion without swelling, then remove the tape and carefully place a gauze under the wings of the needle and re-tape it. However, if the discomfort continues then either try to reposition the needle, or remove it and perform the venepuncture again with a new needle.

• If swelling occurs at the insertion site this usually means that the needle is out of the vein, and the product is leaking into the surrounding tissue, this is known as “infiltration” or “tissuing.” If this happens then remove the needle and perform the venepuncture again, choosing a new site above the swelling, or using your other hand or arm. Don’t worry – the product will be absorbed into the surrounding tissues with no harmful effects.

“Remove or reposition the needle if you experience continued discomfort and try again with a new needle”
• If the infusion will not flow properly then check the following:

1. The bottle is not empty

2. The tubing is not kinked

3. The infusion site and the position of your hand and arm

4. For fluid running down the side of the drip chamber (this can clog the air vent on the tubing and prevent the liquid from being released from the bottle)

5. The height of the drip stand (increased force of gravity can help increase the flow)

• If, when clearing up after the infusion, someone else is accidentally pricked by a needle, encourage the area to bleed, wash under running water, and always inform your referral centre, or doctor.
Will my medicine cause side effects?

The benefit of taking your medicine is expected to be greater than the risk of suffering any unwanted side effects. Most people take medicines without suffering any unwanted side effects, however all medicines can cause problems. Your patient information leaflet (which is included with your medicine) will list all the known side effects linked to your medicine.

Side effects to IVIG infusions

Flebogamma® DIF is well tolerated as shown by the results of clinical studies. However, the product may cause unwanted side effects in some patients, so precautions must be taken to avoid them. The most common side effects happen when the infusion is administered at a faster rate than recommended. Therefore the recommended rate of infusion, as advised by your doctor or referral centre, should always be followed.

Side effects can also occur if you have an infection and you go ahead with your infusion. In this situation, you should consult your doctor or referral centre for advice before proceeding with the infusion.

Type of side effects with IVIG infusions

Side effects with Flebogamma® DIF can be classified in the following way:

Very Common (more than \([\geq]1/10\))
Common (\([\geq]1/100 – less than [\(<]1/10\))
Uncommon (\([\geq]1/1000 - <1/100\))
Rare (\([\geq]1/10,000 - <1/1000\))
Very Rare (\(<1/10,000\)).
Important:

If a side effect has a risk of 1/10,000, then 9,999 out of every 10,000 patients taking the medicine are not expected to experience that side effect.
Will my medicine cause side effects?

A few examples are given below:

**VERY COMMON**
- headache

**COMMON**
- shivers
- nausea
- fever
- back or joint pain
- low blood pressure

*If you experience any of these symptoms, take the following action: either stop or slow the infusion down and inform your doctor or referral centre. If the symptoms stop then the infusion can be continued slowly. Some of the symptoms are treatable; please check with your doctor or referral centre. If the symptoms are severe and/or do not ease once the infusion has been stopped, please contact your doctor or referral centre as soon as possible.*

**UNCOMMON**
- dizziness
- diarrhoea
- chills
- flushing
- vomiting
- wheezing

*If any of these symptoms are experienced, stop the infusion and keep a record of what happened and inform your doctor as soon as possible.*
If you feel or notice any other type of side effect, inform your doctor or referral centre as soon as you can.

In general, side effects are most likely to happen soon after you start a new medicine or after your dose has been increased. Quite often, mild side effects will go away as your body adjusts to the new medicine or dose.

**RARE**
- anaphylactic shock
- reversible aseptic meningitis (inflammation of the membranes covering the brain and spinal cord)
- haemolytic anaemia (a condition where the red cells in the blood break down)
- short-lived skin reactions

**VERY RARE**
- stroke
- deep vein thrombosis
- myocardial infarction

If any of the rare or very rare side effects occur, stop the infusion immediately and dial 999.
The dose and infusion rate of Flebogamma® DIF that you will be given will be worked out by your doctor or referral centre and is specific to you.

The following are general instructions on infusion rates. You must, however, follow the instructions on dose and infusion rate provided by your doctor or referral centre:

The first infusion of Flebogamma® DIF should be at the following rate:

- First 30 minutes: 0.01-0.02 ml/kg body weight per minute.

- If well tolerated, after 30 minutes: increase gradually to the rate advised by doctor or referral centre (which may be up to 0.1 ml/kg body weight per minute for the 5% solution strength and up to 0.08 ml/kg body weight per minute for the 10% solution strength). Do not attempt to increase this rate at home - not everyone can tolerate the maximum rate.

- See chart opposite for drops per minute.
Infusion rate

Maximum rate

Starting rate

Weight (kg)

drops per minute

ml per minute