Flebogamma 5% DIF

Consumer Medicine Information

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT FLEBOGAMMA 5% DIF IS AND WHAT IT IS USED FOR

Flebogamma 5% DIF is a solution for intravenous infusion containing 50 g/l human normal immunoglobulin.

This medicine belongs to the pharmacotherapeutic group called immune sera and immunoglobulins.

Flebogamma 5% DIF is used for:

Treatment of patients who do not have sufficient antibodies (replacement therapy):

- Primary immunodeficiency syndromes such as:
  - congenital agammaglobulinaemia and hypogammaglobulinaemia
  - common variable immunodeficiency
  - severe combined immunodeficiency
  - Wiskott Aldrich syndrome
- Myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections.
- Children with congenital AIDS and recurrent infections.

Treatment of patients with certain inflammatory disorders (immunomodulation):

- Idiopathic thrombocytopenic purpura (ITP), in children or adults at high risk of bleeding or prior to surgery to correct the platelet count.
- Guillain Barré syndrome.

Treatment or prevention of infections after a bone marrow transplantation (allogeneic bone marrow transplantation).

If you have any question about use of Flebogamma 5% DIF please ask your doctor.

2. BEFORE YOU USE FLEBOGAMMA 5% DIF

Do not use Flebogamma 5% DIF

- if you are allergic (hypersensitive) to human normal immunoglobulin or any of the other ingredients of Flebogamma 5% DIF.
  (See special warnings about excipients at the end of this section).
- if you have immunoglobulin A (IgA) deficiency with anti-IgA antibodies.

Take special care with Flebogamma 5% DIF

Certain adverse reactions may occur more frequently:

- in case of high rate of infusion.
- if you have hypo- or agammaglobulinaemia (a condition implying low immunoglobulin levels in your blood) with or without IgA deficiency.
- if you are having Flebogamma 5% DIF for the first time, or it is a long time since your last infusion (e.g. several weeks). You will be watched carefully until an hour after the infusion to detect potential adverse signs.

True hypersensitivity reactions are rare. They can occur in the very seldom cases of IgA deficiency with anti-IgA antibodies.

Rarely, human normal immunoglobulin can induce a fall in blood pressure with allergic reaction, even if you had tolerated previous treatment with human normal immunoglobulin.

Patient with pre-existing risk factors

Please tell your doctor if you have any other condition and illness, as caution is required. In particular, tell your doctor if you have:

- diabetes
- high blood pressure
- history of vascular disease or thrombosis
- overweight problem
- blood volume decrease
- diseases which increase blood viscosity
- advanced age

Patients with a kidney problem

In case of kidney problem, your doctor should consider whether to stop treatment since cases of acute renal failure have been reported in patients receiving IVIg therapy, generally in patients with risk factors.

Tell your doctor, even when any of the above-mentioned circumstances had happened to you in the past.

Special safety warning

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, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove 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 applies to any unknown or emerging viruses or other types of infections.

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

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

It is strongly recommended that every time you receive a dose of Flebogamma 5% DIF the name and batch number of the product are recorded in order to maintain a record of the batches used.

Taking other medicines

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Effects on vaccines: Flebogamma 5% DIF may reduce the effectiveness of certain type of vaccines such as measles, rubella, mumps and varicella.

Effects on blood tests
If you are having a blood test after using Flebogamma 5% DIF, please inform the analyst or your doctor that you have taken this medicine. The level of certain antibodies can rise.

Pregnancy and breast feeding
Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding you must tell your doctor. Your doctor will decide if Flebogamma 5% DIF can be used during pregnancy and lactation.

Driving and using of machines
No effects on ability to drive and use machines have been observed.

Important information about some of the ingredients of Flebogamma 5% DIF

Special warnings about ingredients: This medicine contains 5 g of sorbitol per 100 ml as excipient. You should not use this product if you have fructose intolerance.

3. HOW TO USE FLEBOGAMMA 5% DIF

Flebogamma 5% DIF is given by injection into your veins (intravenous administration). It may be self administered if you have been fully trained by hospital staff. You must make up the infusion in exactly the way you have been shown in order to stop germs getting in. You must never self administer it alone; a responsible adult must be always present.

The dose that you will be given will depend on your weight and will be worked out by your doctor.

At the beginning of your infusion you will receive Flebogamma 5% DIF at a slow rate (0.01-0.02 ml/kg/min). Depending on how comfortable you feel, your doctor may then gradually increase the infusion rate (up to 0.1 ml/kg/min).

The solution should be clear or slightly opalescent. Do not use Flebogamma 5% DIF if you notice that the solution is cloudy or has deposits.

Flebogamma 5% DIF should not be mixed with other medicines or intravenous solutions and it should be administered by a separate intravenous line.

If you use more Flebogamma 5% DIF than you should

If you are given more Flebogamma 5% DIF than you should, tell your doctor or pharmacist immediately.

Overdose may lead to fluid overload and hyper viscosity, particularly in patients at risk, including elderly patients or patients with renal impairment.

Contact poisons information centre on 131126 for advice on management.

If you forget to use Flebogamma 5% DIF

Speak to your doctor or pharmacist immediately and follow his/her instructions.

You must not be given a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flebogamma 5% DIF can cause side effects, although not everybody gets them.

Tell your doctor if any of the following side effects happen during or after the infusion:

- Chills
- Headache
- Fever
- Nausea
- Vomiting
- Allergic reaction
- Joint pain
- Low blood pressure
- Moderate low back pain

Rare side effects:

- A sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even if you have shown no hypersensitivity to previous administration.
- Cases of temporary meningitis (reversible aseptic meningitis)
- Cases of temporary reduction in the number of the red cells in the blood (reversible haemolytic anaemia/haemolysis)
- Cases of transient cutaneous reactions
- Increase in serum creatinine level and/or acute renal failure.

Very rare side effects:

- Thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thromboses.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FLEBOGAMMA 5% DIF

Keep out of the reach and sight of children.

Do not use Flebogamma 5% DIF after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Store below 30 ºC. Do not freeze. Protect form light.

The product should be brought to room or body temperature before use.

The solution should be clear or slightly opalescent. Do not use Flebogamma 5% DIF if you notice that the solution is cloudy or has deposits.

Any unused product or waste material should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Flebogamma 5% DIF contains

The active substance is:

Human normal immunoglobulin (IVIg). One millilitre of Flebogamma 5% DIF contains 50 mg of protein, of which at least 97% is IgG.

The percentage of IgG subclasses is approximately 66.6% IgG_1, 28.5% IgG_2, 2.7% IgG_3 and 2.2% IgG_4.

Contains trace amounts of IgA (lower than 0.05 mg/ml).

The other ingredients are 5% sorbitol and water for injection.

(See section 2. ‘Before you use Flebogamma 5% DIF’ for further information about ingredients).

What Flebogamma 5% DIF looks like and contents of the pack

Flebogamma 5% DIF is a solution for infusion. The solution is clear or slightly opalescent and colourless or pale yellow.

Sizes:

Flebogamma 5% DIF

0.5 g/10 ml, 2.5 g/50 ml, 5 g/100 ml, 10 g/200 ml and 20 g/400 ml vials.

Marketing authorisation holder and manufacturer

Instituto Grifols, S.A.
Can Guasch, 2 - Parets del Vallès
08150 Barcelona - SPAIN

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Grifols Australia Pty Ltd
5/80 Fairbank Road,
Clayton South,
Victoria, Australia
3169

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