Flebogamma 5% DIF

Human normal immunoglobulin (IVIg)

50 mg/ml – Solution for infusion

What is in this leaflet

Please read this leaflet carefully before you start using Flebogamma 5% DIF.

This leaflet answers some common questions about Flebogamma 5% DIF. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Flebogamma 5% DIF against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What 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).

Your doctor may have prescribed Flebogamma 5% DIF for another reason.

Ask your doctor if you have any questions about why Flebogamma 5% DIF has been prescribed for you.

Before you use Flebogamma 5% DIF

When you must not use it

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.

Before you start to use it

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.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Flebogamma 5% DIF. These include:

- Effects on vaccines: Flebogamma 5% DIF may reduce the effectiveness of certain type of vaccines such as measles, rubella, mumps and varicella.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Flebogamma 5% DIF.

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.

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 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.

While you are using Flebogamma 5% DIF

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are receiving Flebogamma 5% DIF.

Things you must not do

Do not give Flebogamma 5% DIF to anyone else, even if they have the same condition as you.

Things to be careful of

Driving and using of machines

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

In case of overdose

If you take too much (overdose)

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.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Flebogamma 5% DIF. Do this even if there are no signs of discomfort or poisoning.

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.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Flebogamma 5% DIF

Storage

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.

Disposal

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.

Product description

What it looks like

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

Flebogamma 5% DIF is supplied as 0.5 g/10 ml, 2.5 g/50 ml, 5 g/100 ml, 10 g/200 ml and 20 g/400 ml vials.

Ingredients

Active ingredient:

- The active ingredient 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).

Inactive ingredients:

- The other ingredients are 5% sorbitol and water for injection. See section “Before you use Flebogamma 5% DIF” for further information about ingredients.

Sponsor Details

Flebogamma 5% DIF is supplied in New Zealand by:

Pharmaco (N.Z.) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060, New Zealand

Telephone (09) 377 3336

Date of Preparation

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