Flebogamma 10% DIF

Human normal immunoglobulin (IVIg)

100 mg/ml – Solution for infusion

What is in this leaflet

Please read this leaflet carefully before you start using Flebogamma 10% DIF.

This leaflet answers some common questions about Flebogamma 10% 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 10% 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 10% DIF is used for

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

- Primary immunodeficiency diseases
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.

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.
- It is used to treat Kawasaki disease, an illness in children where the blood vessels (arteries) in the body become enlarged.

Your doctor may have prescribed Flebogamma 10% DIF for another reason.

Ask your doctor if you have any questions about why Flebogamma 10% DIF has been prescribed for you.

Before you use Flebogamma 10% DIF

When you must not use it

Do not use Flebogamma 10% DIF

- If you are allergic (hypersensitive) to human normal immunoglobulin or any of the other ingredients of Flebogamma 10% DIF (see special warnings about excipients at the end of this section).

- If you do not have enough immunoglobulins of the type IgA in your blood or have developed antibodies to IgA.

- If you have hereditary fructose intolerance, a quite rare genetic condition where the enzyme for breaking down fructose is not produced.

Before you start to use it

Take special care with Flebogamma 10% 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 10% DIF for the first time, or it has been switched from an alternative human normal immunoglobulin (IVIg) product, 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.

Allergic reactions are rare. It may happen particularly if you do not have enough immunoglobulins of the type IgA in your blood or have developed antibodies to IgA.

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/or illness, as caution is required in patients with pre-existing risk factors for clotting (thrombotic) events. 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 10% 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

After receiving Flebogamma 10% DIF, the results of certain blood tests (serological tests) may be interfered for a certain time. If you have a blood test after receiving Flebogamma 10% DIF, please tell the analyst or your doctor that you have been given this medicine.

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 10% DIF can be used during pregnancy and breast-feeding.

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 10% DIF. These include:

- Effects on vaccines: Flebogamma 10% 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 10% DIF.

Important information about some of the ingredients of Flebogamma 10% DIF

Special warnings about ingredients: This medicine contains 5 g of sorbitol per 100 ml as excipient. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine. You should not use this product if you have fructose intolerance. **In babies and young children hereditary fructose intolerance may not yet be diagnosed and may be fatal, thus, they should not receive this medicine.**

How to use Flebogamma 10% DIF

Flebogamma 10% 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 illness and body weight and will be worked out by your doctor.

At the beginning of your infusion you will receive Flebogamma 10% DIF at a slow rate (0.01 ml/kg/min (1 mg/kg/min)). Depending on how comfortable you feel, your doctor may then gradually increase the infusion rate (up to 0.08 ml/kg/min (8 mg/kg/min)).

The solution should be clear or slightly opalescent. Do not use Flebogamma 10% DIF if you notice that the solution is cloudy or has deposits.

Flebogamma 10% DIF should not be mixed with other medicines or intravenous solutions and it should be administered by a separate intravenous line.

Use in children

The dose in children is not considered to be different to that of adults as it will be given depending on the illness and body weight of the children.

If you forget to use Flebogamma 10% DIF

Tell 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 10% 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 10% DIF.

Things you must not do

Do not give Flebogamma 10% DIF to anyone else, even if they have the same condition as you.

Things to be careful of

Driving and using of machines

Dizziness can sometimes occur and might affect the ability to drive and use machines.

In case of overdose

If you take too much (overdose)

If you are given more Flebogamma 10% DIF than you should, your body may take on too much fluid. You may have fatigue, difficult breathing, swelling in the legs and arms, increase in weight or sleeping difficulties. This could particularly happen when you are a patient at risk, e.g. an elderly patient or a patient having problems with your kidneys.

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 10% DIF. Do this even if there are no signs of discomfort or poisoning.

Side Effects

Like all medicines, Flebogamma 10% DIF can cause side effects, although not everybody gets them.

In rare and isolated cases, the following side effects have been reported with immunoglobulin preparations. **Tell your doctor if any of the following side effects happen during or after the infusion:**

- Allergic reactions and isolated cases of 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.
- Thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thromboses.

Three clinical studies with Flebogamma 10% DIF were conducted. In these studies different side effects have been observed. These side effects and frequency are detailed below using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)
- not known (frequency cannot be estimated from the available data)

Very common:
- headache
- nausea
- fever (body temperature increased)

Common:
- red blood cells and white blood cells decreased
- heart rate increase or tachycardia (acceleration of the heart activity)
- cyanosis
- vertigo
- photophobia (excessive sensitivity to light)
- abdominal pain (including abdominal pain upper)
- diarrhoea
- vomiting
- infusion related reaction and infusion site reaction
- infusion site pain
- pain
- rigors (cold shivering sensation)

- tremor/chills (to tremble)
- influenza like illness
- chest discomfort
- feeling cold
- edema peripheral (swelling of extremities due to the accumulation of fluids)
- blood pressure decrease
- blood pressure increase
- haemoglobin decreased (haemoglobin is a substance in the blood which carries oxygen)
- anorexia (lack of appetite)
- myalgia (muscle pain)
- muscle tightness
- back pain
- dizziness (motion sickness)
- radicular syndrome (neck or back pain and other symptoms such as numbness, tingling and weakness in the arms or legs)
- epistaxis
- ecchymosis (large skin hematoma)
- erythema (redness of the skin)
- pruritus (itching)
- rash (eruption of the skin)
- flushing (to blush)
- thrombosis

Uncommon:
- ear pain
- conjunctivitis (inflammation of the conjuntiva of the eyes)
- maculopathy (illness of the macula, in the retina of the eyes)
- abdominal distension
- flatulence
- chest pain
- fatigue
- feeling jittery (nervousness)
- infusion site erythema (redness in the area of injection)
- malaise
- influenza (flu)
- urinary infection
- arthralgia (joint pain)
- muscle spasms
- neck pain
- pain in extremities
- syncope vasovagal (fainting)
- postnasal drip (excessive mucus)
- sinus pain
- wheezing
- acne
- haematoma

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 10% DIF

Storage

Keep out of the reach and sight of children.

Do not use Flebogamma 10% DIF after the expiry date which is stated on the label and carton after EXP.

Store below 30 ºC. Do not freeze. Protect from 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 10% 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 10% DIF is a solution for infusion. The solution is clear or slightly opalescent and colourless or pale yellow.

Flebogamma 10% DIF is supplied as 5 g/50 ml, 10 g/100 ml and 20 g/200 ml.
Pack size of 1 vial.
Not all sizes may be marketed.

Ingredients

Active ingredient:

- The active ingredient is human normal immunoglobulin (IVIg). One ml contains 100 mg of human normal immunoglobulin, of which at least 97% is IgG.

One vial of 50 ml contains: 5 g of human normal immunoglobulin
One vial of 100 ml contains: 10 g of human normal immunoglobulin
One vial of 200 ml contains: 20 g of human normal immunoglobulin

The percentage of IgG subclasses is approximately 66.6% IgG_1, 27.9% IgG_2, 3.0% IgG_3 and 2.5% IgG_4.Contains trace amounts of IgA (lower than 100 micrograms/ml).

Inactive ingredients:

- The other ingredients are 5% sorbitol and water for injection. See section “Before you use Flebogamma 10% DIF” for further information about ingredients.

Sponsor Details

Flebogamma 10% DIF is supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
PO Box 62027
Sylvia Park Auckland 1644, New Zealand

Phone (09) 918 5100

Date of Preparation

This leaflet was reviewed on 16 December 2024.