CONSUMER MEDICINE INFORMATION LEAFLET

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 10% DIF IS AND WHAT IT IS USED FOR

What Flebogamma 10% DIF is

Flebogamma 10% DIF is a solution for intravenous infusion containing 100 g/l human normal immunoglobulin.

Flebogamma 10% 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.

What Flebogamma 10% DIF is used for

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

- Primary Immunodeficiency (PI) Diseases
- Symptomatic hypogammaglobulinaemia secondary to underlying disease or treatment.

Treatment of patients with certain inflammatory disorders (immunomodulation):

- Idiopathic Thrombocytopaenic 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.

If you have any question about use of Flebogamma 10% DIF please ask your doctor.

2. BEFORE YOU USE FLEBOGAMMA 10% DIF

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.

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.

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 10% DIF may reduce the effectiveness of certain type of vaccines such as measles, rubella, mumps and varicella.

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.

Driving and using of machines

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

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.**

3. 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 use more Flebogamma 10% DIF than you should

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. Tell your doctor or pharmacist immediately.

Contact poisons information centre on 131126 for advice on management.

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.

4. POSSIBLE 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 and exfoliative dermatitis
- 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.

5. HOW TO STORE FLEBOGAMMA 10% DIF

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. 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 10% 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 10% DIF contains

- The active substance 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).

- The other ingredients are 5% sorbitol and water for injection. (see section 2 for further information about ingredients).

What Flebogamma 10% DIF looks like and contents of the pack

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 AUST R 184353
10 g/100 ml AUST R 182358
20 g/200 ml AUST R 182359

Pack size of 1 vial.

Not all sizes may be marketed.

Marketing authorisation holder and manufacturer

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08150 Barcelona - SPAIN

Imported and distributed by:

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