Package leaflet: Information for the patient

D-Gam 50 micrograms/ml
D-Gam 250 micrograms/ml

Solution for injection

human anti-D immunoglobulin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or healthcare professional.
- This medicine will be administered to you by your doctor, nurse or healthcare professional.
- If you get any side effects, talk to your doctor, nurse or healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What D-Gam is and what it is used for

D-Gam contains the active ingredient human anti-D immunoglobulin which protects against the effects of Rhesus D (Rh(D)) positive red cells in people who are Rhesus negative.

It is made from blood plasma from screened donors.

D-Gam is used during pregnancy if you are Rh(D) negative to prevent you from becoming sensitised to your baby's red cells if your baby is Rh(D) positive.

D-Gam is also used if you are not pregnant but are Rh(D) negative and are receiving Rh(D) positive cells for any reason to prevent future complications.

D-Gam is given if you are Rh(D) negative and your baby is Rh(D) positive:

- as a routine preventative measure during pregnancy
- soon after any accident or intervention during pregnancy which might lead to bleeding across the placenta
- soon after an abortion when sensitisation is possible
- soon after giving birth

D-Gam can also be given if you are Rh(D) negative and have received blood components containing Rh(D) positive red blood cells to prevent future complications.

Your doctor, nurse or healthcare professional will tell you if it is advisable for you to have D-Gam.

2. What you need to know before you are given D-Gam

Do not use D-Gam:

- if you are allergic (hypersensitive) to human anti-D immunoglobulin or any of the other ingredients of this medicine (listed in section 6)
- if you are known to have antibodies to immunoglobulin A and have had an allergic reaction
- if you are Rh(D) positive

Warnings and precautions

Talk to your doctor, nurse or healthcare professional before you are given D-Gam.

- This medicine must not be injected into the vein, since it may cause a severe reaction if given in this way. Injections must be given to you by your doctor, nurse or healthcare professional into a muscle, usually the shoulder (deltoid).

- For protecting Rh(D) negative women after delivery of a Rh(D) positive baby, this medicine is always given to the mother, not to the new-born baby.

- True allergic reactions to this product are rare, when it is injected into the muscle as directed. Even if you have had this medicine before, you could still have a reaction, for example, low blood pressure and possible shock. In the case of shock, urgent medical advice is needed (see also section 4 'Possible side effects').

- If you are lacking immunoglobulin A (IgA deficient) you might develop antibodies to IgA, although this is not common. If you know you already have antibodies to IgA, tell your doctor, nurse or healthcare professional before your injection.

- If you suffer from high blood pressure, diabetes, a history of cardiovascular disease or a blood/blood related disorder, tell your doctor, nurse or healthcare professional before this medicine is injected.

- If you are having this medicine because you have received Rh(D) positive red cells for whatever reason, you may be given larger doses than those used in pregnancy. Your doctor will assess you for the effects of very rapid break down of the injected red cells.

- Immunoglobulins may increase the risk of having a blood clot, however this has not been seen with D-Gam.

- If you develop pain, swelling and unusual warmth of a limb, sudden shortness of breath and chest pain worsening on deep breathing, numbness or weakness on one side, difficulty with speaking or confusion, contact your doctor or nurse immediately as these symptoms may indicate that you have a blood clot.

- As some medicines may increase the risk of a blood clot, tell your doctor, pharmacist or nurse of all the medicines you are taking.

- Tell your doctor, nurse or healthcare professional if you have any blood tests. This product will raise the level of various antibodies in your blood for several weeks. If you require a blood test during this period, tell your doctor, nurse or healthcare professional when you last had this product injected, as misleading positive results may occur with certain tests.

- This medicine may not work very well in people who are overweight or very overweight. Talk to your doctor, nurse or healthcare professional for advice.

- Large doses (over 5 ml) will be injected into different parts of the body.

Viral Safety

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
- the testing of each donation and pools of plasma for signs of virus/infections
- the inclusion of 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 also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), hepatitis A (HAV) and parvovirus B19 viruses.

Immunoglobulins have not been associated with HAV 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 D-Gam the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Other medicines and D-Gam

Tell your doctor, nurse or healthcare professional if you are taking, have recently taken or might take any other medicines.

Vaccinations
Tell your doctor, nurse or healthcare professional of any vaccinations you have recently had or are about to have.

Besides anti-D, D-Gam provides you with a range of antibodies. These antibodies will interfere with the response to some vaccines, especially MMR (measles, mumps and rubella) and varicella (chickenpox) vaccines. Such vaccinations should be given at least 3 weeks before D-Gam or not until 3 months after. D-Gam is unlikely to contain an antibody to yellow fever; so this vaccine can be given whenever needed.

Pregnancy, breast-feeding and fertility

D-Gam is intended for use in pregnancy and can be used during breast feeding. Immunoglobulins are excreted in human milk and may protect the baby from certain infections.

Driving and using machines

D-Gam has no influence on the ability to drive and use machines.

D-Gam contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

3. How you are given D-Gam

This medicine will be given to you by your doctor, nurse or healthcare professional into a muscle, usually the shoulder (deltoid). Your doctor, nurse or healthcare professional will decide how much D-Gam you should receive.

Injection should be as soon as possible after an accident or intervention during pregnancy and after delivery (ideally within 72 hours).

No other medicines or fluids should be added to this product as their effects on the product have not been established.

If you receive more D-Gam than you should

If you are given more D-Gam than recommended, your doctor, nurse or healthcare professional may carry out some blood tests. It is not known what effects an overdose would have.

If you have any further questions on the use of this medicine, ask your doctor, nurse or healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you feel unwell, tell your doctor immediately. Side effects may occur even if you have previously received human immunoglobulins and tolerated them well.

On rare occasions, (may affect up to 1 in 1,000 people) you may experience a strong allergic reaction or you may experience a sudden drop in blood pressure.

- Tell your doctor or nurse immediately if you find it difficult to breathe, if you feel dizzy and faint or if you develop swellings and a red itchy rash. You may need additional treatment to correct your symptoms.

Tell your doctor or nurse immediately if you feel ill with headaches, high temperature, neck stiffness, mental status changes, nausea and sickness, chills, generalised joint aches and pains or a rash during or within a few days after treatment. You may need additional treatment to correct your symptoms.

Depending on your blood group, you may be more susceptible to your blood being damaged while you are being treated. If this happens your doctor or nurse may want to increase your blood level with blood transfusions.

There may be some short-term discomfort at the site of injection such as swelling, warmth, pain, redness, itching or rash and hardening of the skin.

The following side effects have been reported with human anti-D immunoglobulin.

Not known: frequency cannot be estimated from the available data.

- Tightening of throat or chest
- Wheezing
- Tongue swelling
- Swelling beneath lips and eyes
- Lightheaded, faint or feeling faint
- Hives (urticaria)

- Itching, redness of skin
- Rapid heart beat
- Chills
- Flushing
- Fever
- Headache
- Feeling sick or being sick
- Joint pain
- Back pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.co.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store D-Gam

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the containers after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator ($2^{o}C – 8^{o}C$).

Do not freeze.

Short periods (up to 1 week) of storage at room temperature (25°C), in the dark, will not damage the product.

Do not use this medicine if you notice the solution is cloudy or has deposits.

Your doctor, nurse or healthcare professional will dispose of any solution that remains, along with used syringes, needles and containers.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What D-Gam contains

- The active substance is human anti-D immunoglobulin.
- The other excipients are: sodium chloride, glycine, sodium acetate trihydrate, hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).

Each ml of solution contains at least 250 IU or 1250 IU of human anti-D immunoglobulin. The volume required to give the stated dose is printed on the vial label

What D-Gam looks like and contents of the pack

D-Gam is a clear or slightly yellow or pale brown solution in a clear glass container with a closure to prevent tampering.

Pack sizes

D-Gam 50 micrograms/ml solution for injection
1 x 500 IU vial

D-Gam 250 micrograms/ml solution for injection
1 x 1500 IU vial

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bio Products Laboratory Ltd.
Elstree
Hertfordshire
WD6 3BX
United Kingdom

Manufacturer
Bio Products Laboratory Ltd.
Elstree
Borehamwood
WD6 3BX
United Kingdom

For any information about this medicine, please contact the Marketing Authorisation Holder. Please e-mail: medinfo@bpl.co.uk

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