

Intragam[®] P

Human Normal Immunoglobulin, solution for intravenous infusion.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Intragam[®] P. It does not contain complete information about Intragam[®] P. It does not take the place of talking to your doctor.

If you have any concerns about using this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated.

What Intragam[®] P is used for

Intragam[®] P is manufactured from human plasma (the liquid component of blood) collected by the Australian Red Cross Blood Service. Intragam[®] P is used for patients who need replacement of antibodies which form part of our immune system

and can provide protection against some infections.

Intragam[®] P is also used in diseases when the immune system is overactive, these are called autoimmune disorders.

Ask your doctor if you have any questions about why Intragam[®] P has been prescribed for you. Your doctor will have assessed the risks and benefits for you associated with the use of this medicine.

Before you are given Intragam[®] P

Intragam[®] P must not be used if you have a history of allergy to human immunoglobulin products. Tell your doctor if you have allergies to any other medicines, or if you have ever had an allergic reaction to an injection.

Tell your doctor also if you:

- have previously been advised that you have Immunoglobulin A (IgA) deficiency
- have previously been advised that you have kidney disease

- have a history of heart, or blood vessel disease, or blood clots, have thick blood, have been immobile for some time. Also tell the doctor what medicine you are using as some medicines, such as those that contain the hormone estrogen (for example, birth control pills), may increase your risk of developing a blood clot.
- have previously been treated with immunoglobulin products
- have previously been advised that you have diabetes
- have blood group A, B or AB
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores.
- have any other medical conditions
- are pregnant or breast-feeding
- become pregnant during your treatment
- have had any vaccination within the last two weeks or intend to receive one in the next three months.

If you want further information, consult your doctor.

How to use Intragam® P

Your doctor will determine the dose(s) of Intragam® P that you will receive. Your doctor will give you Intragam® P as an infusion, that is, an injection given slowly into the vein.

Side effects

Along with their intended effects, blood products occasionally cause unwanted effects, some of which are serious. Unwanted effects are more common with the first dose of Intragam® P. Individuals may react differently to similar doses of the same product. This applies to Intragam® P. Most minor effects are related to the rate of infusion and disappear when the rate is slowed down.

Effects associated with Intragam® P

During a clinical trial with Intragam® P in patients who needed replacement of antibodies, some patients experienced headache, migraine, nausea, dizziness or faintness, and tiredness. Reduced red blood cells and iron stores and reduced white blood cells were also reported.

During another clinical trial with Intragam® P in patients with an

overactive immune system, who received larger doses of Intragam® P, some patients experienced headache, nausea, vomiting, shivering, fever, drowsiness, hot flushes, muscle pain, abdominal pain, allergic reactions, reddening of the face or neck, a hot feeling or redness at the site of the injection and increased blood pressure. Reduced red and white blood cells were also reported.

During clinical use of Intragam® P (i.e., not in clinical trials) some patients have also reported skin peeling and redness.

Effects associated with similar products

Unwanted effects which may occur include stomach pain, headache, chest tightness, flushed or pale face, feeling hot or unwell, shortness of breath or breathing difficulty, skin rash, itching, general redness, swelling, faintness, dizziness, nausea or vomiting or a hot feeling or redness at the site of the injection. Should any of these effects develop during infusion, the doctor will take appropriate action.

Some patients may develop delayed unwanted effects such as nausea, vomiting, chest pain, chills or shivering, dizziness, aching legs or joint pain. These effects may occur after the

infusion has stopped but usually within 24 hours.

A condition called aseptic meningitis syndrome has been reported to occur infrequently in association with infusions similar to Intragam® P. It usually begins within several hours to two days following treatment. The signs include severe headache, neck stiffness, drowsiness, fever, inability to stand bright light, painful eye movements, and nausea and vomiting. The condition reverses without ill effects when treatment is stopped.

There have been reports that the kidneys, liver and blood vessels (thrombosis) may be affected with infusions similar to Intragam® P. These occurrences are extremely rare.

If you experience any of the mentioned effects or any other abnormal signs after treatment, contact your doctor immediately.

Contact your doctor immediately if you experience any of these symptoms at any time: fever, loss of appetite, extreme tiredness, dizziness, paleness of skin, stomach pain, jaundice (yellow skin and eyes), dark urine, joint pain, skin rashes, shortness of breath, chest pain, weakness or numbness on one side of the body and pain/tenderness,

swelling/discolouration of an arm or leg.

Intragam[®] P can interfere with some live vaccines (e.g. measles and polio), even up to three months later. Advise your doctor if you are to receive other vaccines within three months of receiving Intragam[®] P.

About blood products

This product is made from human plasma obtained from voluntary donors. When products are made from human blood and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or parvovirus B19 and theoretically the Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents some of which may not yet have been discovered.

To reduce the risk of this happening, extra steps are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to remove and kill certain viruses. This special treatment is considered effective against viruses known as enveloped viruses such as HIV and hepatitis B and C viruses, and

the non-enveloped virus, hepatitis A. These procedures may be of limited value against the non-enveloped virus, parvovirus B19. However, the product contains specific antibodies directed against parvovirus B19. Parvovirus B19 is a virus causing respiratory irritation, commonly affecting children.

Despite the measures taken, the risk of viral and other agents' infectivity cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this product with your doctor.

Interference with glucose estimations

The maltose present in Intragam[®] P may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. If this glucose measurement is used to guide treatment, hypoglycaemia may occur. Only certain glucose tests have been implicated, so when monitoring glucose levels consult your doctor to ensure that maltose does not interfere with the blood glucose reading of the test you are using.

Infusion of Intragam[®] P may also result in elevated levels of glucose in the urine for a short period of time.

If you want further information, or if you are worried about any other symptoms after the infusion, consult your doctor.

Overdose

Administering a larger than recommended dose may lead to thickening of the blood and expansion of the blood volume, particularly in elderly patients and patients with kidney problems.

Storing Intragam[®] P

Store at 2°C to 8°C (Refrigerate. Do not freeze). Once removed from refrigeration, store below 25°C and use within 3 months. Protect from light.

Do not use after the expiry date.

Further information

Intragam[®] P can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about Intragam[®] P. If you require further information about Intragam[®] P and your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

Product description

What it looks like

Intragam[®] P is a clear, colourless, non-viscous (not thick) solution. It is available in glass bottles.

Ingredients

In each vial of Intragam[®] P is a sterile solution containing 6% blood proteins of which at least 98% is immunoglobulins. It also contains 10% maltose (a sugar).

Manufacturer

Intragam[®] P is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189–209 Camp Road
Broadmeadows VIC 3047
Australia

Distributor

Australian Red Cross Blood Service

Date of revision

November 2018

Australian Register Numbers

10 mL: AUST R 68635

50 mL: AUST R 68632

200 mL: AUST R 68633

500 mL: AUST R 68634

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