1.3.2 Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Intragam 2 ml/ 5 ml, 160 g/L, Human normal immunoglobulin (solution for intramuscular injection).

Read all of this leaflet carefully before you are given Intragam 2 ml/5 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

Intragam 2 ml/5 ml has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT INTRAGAM 2 ML/5 ML CONTAINS

Intragam 2 ml/5 ml is a solution containing a normal variety of antibodies. It is prepared from human plasma from healthy, unpaid donors and therefore has antibodies to a wide range of infectious organisms to which these donors have been exposed.

The active substance is human protein.

Each milliliter of **Intragam 2 ml/5 ml** contains 160 mg of human protein (at least 90 % of which is gamma globulin, a type of blood plasma protein that includes antibodies). **Intragam 2 ml/5 ml** contains at least 100 IU/ml of antibodies to the hepatitis A virus.

The other ingredient is glycine, which is added as a stabiliser.

It does not contain any preservatives.

2. WHAT INTRAGAM 2 ML/5 ML IS USED FOR

Intragam 2 ml/5 ml is used:

- To protect you against hepatitis A infection if you have been exposed to the virus or may be exposed to the virus e.g. by travelling to areas in which the virus is common.
- To protect you against a wide variety of infections when you have insufficient levels of your own antibodies. This is because you have a condition that prevents you from making your own antibodies, called antibody deficiency.

Your doctor will explain further why this medicine has been given to you.

3. BEFORE INTRAGAM 2 ML/5 ML IS ADMINISTERED

Do not administer Intragam 2 ml/5 ml:

- If you are allergic to any of the ingredients in this medicine. Your doctor will decide if you should be given this medicine in this case.

Tell your doctor or healthcare professional before being given the injection:

- If you are suffering from any blood disorders which interfere with clotting.
- If you have a selective deficiency of immunoglobulin A (IgA) as the small amounts of IgA in this preparation may cause an allergic reaction the next time you are given this medicine.
- If you have had a severe allergic reaction to plasma products.
- If you have had any vaccinations recently or you are about to have any vaccinations. Tell your doctor if this is the case.
- If you are going for a blood test, as this medicine may lead to misleading results. Tell your doctor if this is the case.

Your doctor will decide if you should be given this medicine in these cases.

Receiving Intragam 2 ml/5 ml with food and drink:

Intragam 2 ml/5 ml is injected directly into the muscle and is not affected by food or drink.
Pregnancy and breast-feeding:

Tell your doctor if you are pregnant, think you may be pregnant, or are breast feeding and he will determine if it is safe for you to be given this medicine.

Driving and using machinery:

There are no known effects of this medicine on your ability to drive or use machinery.

Important information about some of the ingredients of Intragam 2 ml/5 ml:

Intragam 2 ml/5 ml is prepared from human plasma. When medicinal products prepared from human plasma are given to patients, the risk of infectious diseases by certain viruses cannot be totally ruled out. This also applies to any unknown or new viruses or other types of infections. Several different steps have been taken to make this possibility very unlikely. 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. Each unit of plasma is tested for antibodies to human immunodeficiency virus (HIV), hepatitis C virus (HCV) and hepatitis B surface antigen (HBsAg) using approved methods. In addition, all plasma pools are tested for these viruses and antibodies to these viruses. Only plasma in which no evidence of these viruses is found is used in the manufacture of **Intragam 2 ml/5 ml.**

The manufacturing process also involves steps which are aimed at removing/inactivating virus. The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV. The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus and parvovirus B19.

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 **Intragam 2 ml/5 ml**, the name and batch number of the product are recorded in order to maintain a record of the batch used.

Please speak to your doctor should you require additional information in this regard.

Using other medicines with Intragam 2 ml/5 ml:

Intragam 2 ml/5 ml should not be mixed with other medicinal products for injection when being given to you.

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines).

4. HOW TO RECEIVE INTRAGAM 2 ML/5 ML

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself **Intragam 2 ml/5 ml.** It will be given to you by a person who is qualified to do so.

This product must always be injected by a doctor or nurse. **Intragam 2 ml/5 ml** must never be injected into a vein. It must be injected slowly into a large muscle.

Your doctor will tell you how long your treatment with **Intragam 2 ml/5 ml** will last.

Doses:

Protection against hepatitis A virus:

0,02 ml/kg – if you are going to be staying in an area where hepatitis A virus is common, for less than 3 months.

0,06 ml/kg – every 4 to 6 months if you are going to be staying for longer than 3 months.

0,02 to 0,04 ml/kg – if you have been in contact with someone with hepatitis A (within 1 week of

contact).

Replacement of antibodies in antibody deficiency:

0,2 to 0,5 ml/kg repeated every 4 to 8 weeks or as necessary.

If you use more Intragam 2 ml/5 ml than you should:

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

Your dosage is calculated by your doctor but if you feel unwell after being given this medicine, you should consult your doctor.

Effects when treatment with Intragam 2 ml/5 ml is stopped:

In certain cases, if injection of **Intragam 2 ml/5 ml** is stopped, the success of your treatment may be at risk. Your doctor will decide when treatment should be stopped.

5. POSSIBLE SIDE EFFECTS

Intragam 2 ml/5 ml can cause side effects.

The following have been reported after injection:

Headache, fever, chills, redness of the face, lightheadedness, backache, nausea and skin reactions. If you get any of these or just feel unwell after getting the injection, you must consult your doctor or other healthcare professional.

As with all intramuscular injections, there may be some short-term discomfort at the site of injection.

Allergic reactions, such as breathing difficulties, faintness, and possibly shock can occur rarely. Your doctor will have the medicines required to treat this when giving you **Intragam 2 ml/5 ml.**

Not all side effects reported for **Intragam 2 ml/5 ml** are included in this leaflet. Should your general

health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF INTRAGAM 2 ML/5 ML

Keep all medicines out of the reach and sight of children.

This medicine should be stored in its carton to protect it from light. It must be stored in the refrigerator (between 2 and 8 degrees celsius) and should not be frozen.

Disposal:

After injection of the correct dose, your doctor or nurse will dispose of any solution that remains, along with used syringes, needles and containers, according to correct procedures.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF INTRAGAM 2 ML/5 ML

Intragam 2 ml/5 ml comes in a sterile, clear, colourless, 2 ml or 5 ml glass ampoule.

8. IDENTIFICATION OF INTRAGAM 2 ML/5 ML

Intragam 2 ml/5 ml is a clear to slightly cloudy, pale yellow to light brown sterile solution.

9. REGISTRATION NUMBER

Intragam 2 ml: T/30.2/740

Intragam 5 ml: T/30.2/741

10. NAME AND ADDRESS OF REGISTRATION HOLDER

NATIONAL BIOPRODUCTS INSTITUTE

PRIVATE BAG X9043

PINETOWN

3600

10 EDEN RD

PINETOWN

3610

Telephone: 086 016 2472

Telefax: 031 708 5614

11. DATE OF PUBLICATION

Approval date: 26/03/2012

Regulation 10 amendment date: 27/03/2015