1.3.2 Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Polygam® 1 g (3 g) (6 g) (12 g) Polyvalent human normal immunoglobulin, **1 g, 3 g, 6 g & 12 g**, lyophilised powder for IV infusion

Read all of this leaflet carefully before you are given Polygam

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

Polygam comes in 4 different pack sizes. Each bottle contains human normal immunoglobulin, the active part of your medicine, in different amounts. It contains mainly immunoglobulin G (IgG), but also small amounts of IgA and IgM. It is obtained from human plasma of healthy, volunteer, unpaid donors.

The active substance is: Polyvalent human normal immunoglobulin

Polygam 1 g contains 1 g polyvalent human normal immunoglobulin per 50 ml bottle.

Polygam 3 g contains 3 g polyvalent human normal immunoglobulin per 100 ml bottle.

Polygam 6 g contains 6 g polyvalent human normal immunoglobulin per 200 ml bottle.

Polygam 12 g contains 12 g polyvalent human normal immunoglobulin per 400 ml bottle.

The other ingredient is sucrose (in different amounts) which is added as a stabiliser.

It does not contain any preservatives.

2. WHAT POLYGAM IS USED FOR

This medicine is used to replace antibodies which are missing in primary antibody deficiency syndromes (lack of certain proteins protective against infection that you may either have been born with or may develop during life).

It is also used to replace antibodies in secondary antibody deficiencies caused by lymphocytic leukaemia and other bone marrow cancers, and in children born with AIDS when repeated infections occurs. The medicine is also used for the treatment of Idiopathic Thrombocytopenic Purpura (a blood cell, platelet, disorder), Kawasaki disease (disorder of the blood vessels and heart in children), Guillain Barré syndrome (disorder of the nervous system) and as an immunoglobulin supplement during bone marrow transplantation.

3. BEFORE POLYGAM IS ADMINISTERED

Do not administer Polygam:

- If you are hypersensitive (allergic) to immunoglobulins or to any of the other ingredients of **Polygam**. Your doctor will consider your illness versus the risk of an allergy and advise you regarding the use of the treatment.

- If you have antibodies to IgA or if you only lack IgA – **Polygam** may cause a severe allergic reaction in this situation. Your doctor will advise you if this affects you.

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

- If you have kidney problems or are at higher risk for kidney problems. If you are diabetic, overweight, elderly, have an infection, a kidney disorder, or are taking other medicines, tell your doctor before taking this medicine. In these patients, **Polygam** may add to the pre-existing risk of developing kidney failure and your doctor will advise if you should be given the medicine. At-risk patients may need to be given a lower dose of the medicine,

and avoid the use of certain water tablets (diuretics) while taking **Polygam.** The doctor will also need to ensure that you are adequately hydrated and may also want to monitor your urine output before and after using this medicine.

- If you have heart disease or problems with blood clotting – this medicine may cause blood clots to form more easily in the blood vessels.
- If you get an allergic or shock reaction, your doctor will have medication available to treat this.
- For patients whose heart does not function properly, the large volumes in high doses of **Polygam** may be a problem. Your doctor will advise you if this affects you.

Receiving Polygam with food and drink:

Polygam is infused directly into the vein and is not affected by food or drink.

Pregnancy and breast-feeding:

The safety of **Polygam** for use during pregnancy has not been established. Immunoglobulins are excreted into the breast milk. If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking this medicine.

Driving and using machinery:

Polygam may cause faintness. Make sure you know how this medicine affects you before you drive or operate machines.

Important information about some of the ingredients of Polygam:

Human normal immunoglobulin 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, including some which may not have yet been discovered. To reduce the risk from such viruses, strict measures are applied to the selection and testing of blood donors and donations. Each unit of plasma is tested for antibodies to human immunodeficiency virus (HIV), hepatitis C virus and hepatitis B surface antigen using approved methods. Only plasma in which no evidence of these viruses is found is used. In addition, the pooled plasma is also tested for the presence of these viruses and only processed further if the virus is not found.

The manufacturing process also involves steps which are aimed at removing/killing virus. Please speak to your doctor should you require additional information in this regard.

The sucrose in **Polygam** is excreted unchanged in the urine after intravenous (IV) administration. Patients with sugar diabetes (diabetes mellitus) do not need to adjust their diabetes medicines while taking this medicine.

Using other medicines with Polygam:

Polygam should not be taken together with:-

- Live virus vaccines - **Polygam** may lessen the effectiveness of live virus vaccines such as measles, rubella, mumps and chickenpox vaccines. Wait at least 3 months after receiving **Polygam** before taking a live virus vaccine. In the case of measles, you may need to wait for up to 1 year before receiving a measles vaccine. It may be necessary, after vaccination, to have the measles antibody status checked to confirm that you have immunity to measles.
- This medicine will raise the level of various antibodies in your blood for several weeks or longer. If you require a blood test during this period, tell your doctor when you last had this product injected as misleading positive results may occur with certain tests.

Do not mix **Polygam** with any other medicines in the same solution for IV infusion.

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

4. HOW TO RECEIVE POLYGAM

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

You will not be expected to give yourself **Polygam.** It will be given to you by a person who is qualified to do so.

Polygam is given by infusing into a vein and should be administered only by your doctor or other health care professional. Always use **Polygam** exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

Dosage

- The usual dose and dosing interval of **Polygam** depends on the illness being treated and your response to the medicine. Your doctor will determine the dose and dosing intervals that are appropriate for you.
- For the treatment of Kawasaki disease, aspirin may need to be given as well. Your doctor will decide if you should be given aspirin and the appropriate dose.
- Your doctor may want to record the batch number of your medicine in your file.

How to dissolve this medicine:

This medicine should only be dissolved with the solution provided (sodium chloride).

Your doctor or other health care professional would dissolve the medicine before giving it to you. This may take up to 30 minutes.

Do not use if the medicine appears cloudy or discoloured.

How will the medicine be given:

The medicine is given by infusing into a vein through a filter, using an administration set. It should be given immediately after it is dissolved.

Your doctor will determine the infusion rate that is suitable for you based on your body weight. Once this has been set, it should not be changed except by your doctor or nurse.

Side effects are more likely if the medicine is infused too fast into a vein. If side effects do occur the infusion should be slowed or stopped until the symptoms disappear.

If you use more Polygam than you should:

Overdose may lead to fluid overload and a thickening of the blood, especially in high-risk patients such as the elderly and those with kidney problems.

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.

Treatment is symptomatic and supportive.

Effects when treatment with Polygam is stopped:

Your doctor will decide when it is suitable for this medicine to be stopped. In certain conditions, there may be a re-occurrence of symptoms when stopped. Please consult your doctor if you feel unwell.

5. POSSIBLE SIDE EFFECTS

Polygam can have side effects. Side effects are more likely in patients who receive the medicine for the first time, if the product is switched to another human normal immunoglobulin product or when there has been a long interval since the last infusion. Side effects are also more likely if this medicine is infused too fast into the vein. If you feel unwell while on this medicine, you should consult your doctor or other health care professional.

The main reactions which may occur during infusion or in the next few hours are rash, faintness, fever, headache, low blood pressure and breathing problems.

Other less common reactions can include skin and other allergic reactions, pain at the injection site, joint pains, nausea and vomiting, increased heart rate, leg cramps, backache, chills, tiredness and a general feeling of being unwell. If any of these side effects continue, are severe or bother you, speak to your doctor or other health care professional.

Other reactions can occur but are rare for example a burning sensation in the head, a sudden fall in blood pressure which could lead to shock, blood clotting problems, destruction of red blood cells and decreased kidney function.

Some patients may develop severe headache several hours to a few days after receiving intravenous immunoglobulin preparations. Also, there may be dislike of bright light, vomiting, fever and stiff neck. This is more likely in patients with a history of migraine or those treated with higher doses of **Polygam**. Contact your doctor immediately should any of these side effects occur.

Not all side effects reported for **Polygam** 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 of pharmacist.

6. STORING AND DISPOSING OF POLYGAM

Store in a dry and cool place at or below 25 °C.

Protect from light.

Store all medicines out of the reach of children.

Discard any unused product. Your doctor will do this.

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

7. PRESENTATION OF POLYGAM

Each pack consists of a clear glass bottle containing freeze-dried immunoglobulin powder,

bag(s) of 0,9 % *m/v* sodium chloride diluent and a reconstitution set. The following pack sizes are available:

1 g immunoglobulin with 1 x 50 ml normal saline bag

3 g immunoglobulin with 2 x 50 ml normal saline bags

6 g immunoglobulin with 2 x 100 ml normal saline bags

12 g immunoglobulin with 2 x 200 ml normal saline bags

8. IDENTIFICATION OF POLYGAM

Freeze-dried powder: a white powder with no specific shape.

Dissolved solution: slightly opalescent solution.

9. REGISTRATION NUMBERS

Polygam® 1 g **Z/30.2/367**

Polygam® 3 g **Z/30.2/368**

Polygam® 6 g **Z/30.2/369**

Polygam® 12 g **29/30.2/511**

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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