Physician’s leaflet

**Omr-IgG-am™ 5% IV**
Nanofiltered and SD virus inactivated
The method of preparation includes a step to remove detectable thrombosis-generating agents

**Composition:**
Omr-IgG-am™ 5% IV is a sterile solution containing 5% protein (50 mg in 1 ml solution of which at least 95% is Human Normal Immunoglobulin G as the active ingredient), 10% maltose and Water for Injections. The Immunoglobulin A (IgA) content is ≤ 0.15mg/ml.

Omr-IgG-am™ 5% IV does not contain Sucrose. No preservatives are added.

**Description**
Omr-IgG-am™ 5% IV is manufactured from human plasma by Cohn (ethanol) fractionation (this step has been shown in literature to be a primary virus inactivation step). After a first ultra- /diafiltration, the product undergoes a second virus inactivation step by the solvent-detergent method using TnBP/Triton-X-100, and a third inactivation by nanofiltration at pH-4. **Manufacturing process includes a specific step to remove detectable thrombosis-generating agents** (see Warnings and Special Precautions).

**Pharmaceutical Form**
Omr-IgG-am™ 5% IV is a clear or slightly opalescent, almost odorless, colorless to pale yellow liquid for intravenous infusion.

**Pharmacological Properties**

*Pharmacodynamic properties*
As Human Normal Immunoglobulin, the product contains mainly IgG having a broad spectrum of antibodies against various infectious agents (viruses and bacteria) currently prevalent in the population. Opsonization and neutralization of micro-organisms and toxins have been documented. **Omr-IgG-am™ 5% IV contains all the immunoglobulin G activities which are present in the normal population.** It is prepared from pooled source material from not fewer than 1000 prescreened donors.

The product has a distribution of IgG sub-classes closely proportional to that of normal human plasma.

Adequate doses of this medicinal product may restore abnormally low IgG levels to the normal range. The mechanism of action in idiopathic thrombocytopenic purpura is not fully elucidated, but includes immunomodulatory effects.

*Pharmacokinetic properties*
Human Normal Immunoglobulin IV is immediately and completely bioavailable in the recipient’s circulation after intravenous administration. It is distributed relatively rapidly between plasma and extravascular fluid; after approximately 3-5 days an equilibrium is reached between the intra- and extravascular compartments.

Human Normal Immunoglobulin IV has a half-life of between 26 and 32 days. This half-life may vary from patient to patient, in particular in primary immunodeficiency.

Immunoglobulin G (IgG) and IgG-complexes are broken down in cells of the reticuloendothelial system.

**Preclinical safety data**
Immunoglobulins are normal constituents of the human body.
In animals, single dose toxicity testing is of no relevance and higher doses result in fluid overloading. Repeated dose toxicity testing and embryo-foetal toxicity studies are impracticable due to induction of, and interference with antibodies. Effects of the product on the immune system of the new-born have not been studied.

Since clinical experience provides no indication of tumorigenic or mutagenic effects of immunoglobulins, experimental studies, particularly in heterologous species, are not considered necessary.

Virus inactivation of Omr-IgG-am™ 5% IV has been carried out using solvent/detergent (SD) method with tri-n-butyl phosphate (TnBP) and Triton-X-100. These SD reagents are removed during the purification process.

At the doses at which Omr-IgG-am™ 5% IV is administered, no toxic effects have occurred with these reagents in animal studies of single dose and repeated dose toxicity, and of reproduction toxicity.

**Therapeutic Indications**

- **Replacement Therapy**
  - Primary immunodeficiency (patients with primary defective antibody synthesis such as agammaglobulinemia or hypogammaglobulinemia)
  - Multiple Myeloma or Chronic Lymphocytic Leukemia (CLL) with severe secondary hypogammaglobulinemia and recurrent infections.
  - Children with congenital AIDS and recurrent infections

- **Immunomodulation**
  - Idiopathic Thrombocytopenic Purpura (ITP)
  - Guillain Barré Syndrome
  - Kawasaki Disease

- **Allogenic Bone Marrow Transplantation**

**Contraindications**

Omr-IgG-am™ 5% IV is contra- indicated in individuals who are known to have anaphylactic or severe systemic response to intramuscular or intravenous immunoglobulin preparations or to any of the excipients.

As with other immunoglobulin preparations Omr-IgG-am™ 5% IV should not be given to patients with antibodies to IgA or selective IgA deficiency.

**Warnings and Special Precautions**

**General**

Any vial that has been entered should be used promptly. Partially used vials should be discarded. Do not use if turbid.

Solutions which have been frozen should not be used.

Adequate hydration prior to the initiation of IVIG infusion is required.

Potential complications can often be avoided by ensuring that patients:

- Are not sensitive to human immunoglobulin by initial injecting the product slowly.
- Are carefully monitored for any symptoms throughout the infusion period. In particular patients naive to human immunoglobulin, patients switched from an alternative IVIg product or when there has been a long interval since the previous infusion should be monitored during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs. All other patients should be observed for at least 20 minutes after administration.

Certain severe adverse drug reactions may be related to the rate of infusion, therefore recommended infusion rate given under “Dosage and Administration” must be closely followed.

In all patients, IVIg administration requires:

- adequate hydration prior to the initiation of the infusion of IVIg
- monitoring of urine output
- monitoring of serum creatinine levels
- avoidance of concomitant use of loop diuretics
Patients naive to immunoglobulin G (IgG)
Patients naive to immunoglobulin G (IgG) usually experience a higher frequency of events than those well maintained on regular therapy. The recommended infusion rate given under “Dosage and Administration” must be closely followed and patients must be closely monitored and carefully observed for any symptoms throughout the infusion period, and for 1 hour after the first infusion. In case of adverse reactions either the rate of administration must be reduced or the infusion stopped until symptoms disappear.

If severity of reactions persists after discontinuation of the infusion, appropriate treatment is recommended.

In case of anaphylactic reaction or shock, treatment should follow the guidelines for shock therapy. Epinephrine should be available for the treatment of any acute anaphylactoid reactions.

Patients with agammaglobulinemia or extreme hypogammaglobulinemia
Patients with agammaglobulinemia or extreme hypogammaglobulinemia who have not received immunoglobulin therapy within the preceding 8 weeks may be at risk of developing inflammatory reactions upon the infusion of human immunoglobulins. These reactions are manifested by a rise in temperature, chills, nausea and vomiting, and appear to be related to the rate of infusion.

Hypersensitivity
True hypersensitivity reactions are rare. They can occur in patients with anti-IgA antibodies.

IVIg is not indicated in patients with selective IgA deficiency where the IgA deficiency is the only abnormality of concern.

Rarely, human normal immunoglobulin can induce a fall in blood pressure with anaphylactic reaction, even in patients who had tolerated previous treatment with human normal immunoglobulin.

Acute Renal Failure
Cases of acute renal failure have been reported in patients receiving IVIg therapy. In most cases, risk factors have been identified, such as pre-existing renal insufficiency, systemic lupus erythematosus, diabetes mellitus, hypovolaemia, overweight, concomitant nephrotoxic medicinal products or age over 65.

In patient with above risk, factors creatinine levels should be measured for 3 days after intravenous immunoglobulin infusion.

In patients at risk of acute renal failure, IVIg products should be administered at the minimum rate of infusion and dose practicable.

In case of renal impairment, IVIg discontinuation should be considered.

Hemolysis
Heightened awareness of the potential for hemolysis is recommended in individuals receiving immune globulin products, particularly those who are determined to be at increased risk.

Patients at increased risk for hemolysis following treatment with immune globulins include those with non-O blood group types, those who have underlying associated inflammatory conditions, and those receiving high cumulative doses of immune globulins over the course of several days.

Patients receiving immune globulin products should be monitored for hemolysis, particularly those at increased risk.

Clinical symptoms and signs of hemolysis include fever, chills and dark urine. If these occur, appropriate laboratory testing should be obtained.

Thromboembolic Events
Despite the new step to remove detectable thrombosis-generating agents, there is clinical evidence of an association between IVIg administration and thromboembolic events such as myocardial infarction, cerebral vascular accident (including stroke), pulmonary embolism and deep vein thrombosis which is assumed to be related to a relative increase in blood viscosity through the high influx of immunoglobulin in at-risk patients. Care should be used when immune globulin products are given to individuals determined to be at increased risk of thrombosis.

Caution should be exercised in prescribing and infusing IVIg in obese patients and in patients with pre-existing risk factors for thromboembolic events (such as acquired or hereditary hypercoagulable states, prolonged immobilization, in dwelling vascular catheters, advanced age, estrogen use, hypertension, diabetes mellitus and, a history of venous or arterial thrombosis, cardiovascular risk factors (including history of atherosclerosis and/or impaired cardiac output) and hyperviscosity (including cryoglobulins, fasting chylomicronemia and/or high triglyceride levels, and monoclonal gammapathies), vascular disease or thrombotic episodes, acquired or inherited thrombophilic disorders, or patients with prolonged periods of immobilisation, severe hypovolemia, or with diseases which increase blood viscosity).

Patients at risk for thrombosis should receive immune globulin products at the slowest infusion rate practicable, and these individuals should be monitored for thrombotic complications. Consideration should also be given to measurement of baseline blood viscosity in individuals at risk for hyperviscosity.
An aseptic meningitis syndrome (AMS) has been reported to occur infrequently in association with Immune Globulin Intravenous (Human) treatment. The syndrome usually begins within several hours to two days after infusion. It is characterized by symptoms and signs including severe headache, nuchal rigidity, drowsiness, fever, photophobia, painful eye movements, nausea and vomiting. Cerebrospinal fluid studies are frequently positive with pleocytosis up to several thousand cells per mm$^3$, predominantly from the granulocytic series, and elevated protein levels up to several hundred mg/dL. Patients exhibiting such symptoms and signs should receive a thorough neurological examination, including CSF studies, to rule out other causes of meningitis. AMS may occur more frequently in association with high dose (2g/kg) Immune Globulin Intravenous (Human) treatment. Discontinuation of Immune Globulin Intravenous (Human) treatment has resulted in remission of AMS within several days without sequelae.

Products made from plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by effective donor screening, testing for the presence of certain current virus infections, by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit diseases. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent.

It is strongly recommended that every time that Omr-IgG-am is administered to a patient, the name and batch number of the product be recorded in order to maintain a link between the patient and the batch of the product. For this purpose a sticker with the batch identification will be added to each Omr-IgG-am vial.

See 'Drug interactions and other forms of interactions' for information regarding blood glucose testing.

Drug interactions and other forms of interactions
• Live attenuated vaccines
Immunoglobulin administration may impair for a period of at least 6 weeks and up to 3 months the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella. After administration of this medicinal product, an interval of 3 months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to 1 year. Therefore patients receiving measles vaccine should have their antibody status checked.
• Interference with serological testing
Passive transmission of antibodies to erythrocyte antigen- e.g. A,B or D may interfere with some serological tests- e.g. Coomb's test, haptoglobin, reticulocyte count.
• Incompatibilities
Omr-IgG-am ™ 5 % IV should not be mixed with other medicinal products. A separate intravenous line should be used for the infusion.

Omr-IgG-am ™ 5 % IV contains maltose which can be misinterpreted as glucose by certain types of blood glucose testing systems (for example, by systems based on GDH-PQQ or glucose-dye-oxidoreductase methods). Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific, should be used to test or monitor blood glucose levels in patients receiving maltose-containing parenteral products, including Omr-IgG-am 5% IV.

The product information of the blood glucose testing system, including that of the test strips, should be carefully reviewed to determine if the system is appropriate for use with maltose-containing parenteral products. If any uncertainty exists, contact the manufacturer of the testing system to determine if the system is appropriate for use with maltose-containing parenteral products. The interference of maltose in blood glucose assays may result in falsely elevated glucose readings and, consequently, in the inappropriate administration of insulin, resulting in life threatening hypoglycaemia and death.

Pregnancy and lactation
Pregnancy
The safety of this medicinal product for use in human pregnancy has not been established in controlled clinical trials and therefore should only be given with caution to pregnant women and breast-feeding mothers. IVlg products have been shown to cross the placenta, increasingly after the third trimester. Clinical experience with immunoglobulins suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

Breast-feeding
Immunoglobulins are excreted into the milk and may contribute to protecting the neonate from pathogens which have a mucosal portal of entry.

Effects on ability to drive and use machines
The ability to drive and operate machines may be impaired by some adverse reactions associated with Omr-IgG-am. Patients who experience adverse reactions during treatment should wait for these to
resolve before driving or operating machines.

**Adverse reactions**
During or shortly after the application of intravenous immunoglobulins minor side effects such as headache, chills, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate back pain may occur occasionally. Dyspnea and tachycardia may occur more frequently and require medical attention. Reversible aseptic meningitis and nephrotoxicity have occurred rarely. Rarely immunoglobulins may cause a fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no sensitivity to previous administration. Slowing or stopping the infusion should allow the symptoms to disappear promptly. Thereafter the infusion may be started again using a lower infusion rate. Allergic and anaphylactic reactions necessitate immediate cessation of the infusion. Less severe reactions may be controlled with glucocorticoids and/or antihistamines. When severe reactions occur, treatment for shock must be initiated according to current guidelines. For this purpose, see the recommendations given in the following table.

**Immediate measures to be taken in case of intolerable reactions:**

<table>
<thead>
<tr>
<th>Clinical symptoms</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjective complaints (backache, nausea, etc.)</td>
<td>Stop infusion</td>
</tr>
<tr>
<td>Skin symptoms (flush, urticaria, etc.)</td>
<td>Antihistamines</td>
</tr>
<tr>
<td>Tachycardia, moderate drop in blood pressure (below 90 mm Hg systolic)</td>
<td>Glucocorticoids i.v. (100-500 mg prednisolone)</td>
</tr>
<tr>
<td>Dyspnea Shock</td>
<td>Dopamine continuous infusion (2-4 μg/kg/min) high doses of glucocorticoids i.v. (up to 1 g prednisolone [water soluble]), oxygen, volume expander, possibly increased diuresis using furosemide in case of normovolaemia, control of acid base balance and electrolytes (if necessary, correct).</td>
</tr>
<tr>
<td>Persistent normovolaemic shock</td>
<td>Dopamine dosage up to a maximum of 10 μg/kg/min possibly in combination with noradrenalin.</td>
</tr>
</tbody>
</table>

When medicinal products prepared from human blood or plasma are administered infectious diseases due to transmission of infective agents cannot be totally excluded. This also applies to pathogens of hitherto unknown nature. To reduce the risk of transmission of infective agents, selection of donors and donations by suitable measures is performed, plasma pools are tested, and removal and/or inactivation procedures are included in the production process.

The Omr-IgG-am ™ 5% IV manufacturing process contains 3 virus inactivation steps: Cohn fractionation (ethanol), solvent/detergent treatment (TnBP + Triton-X-100) and nanofiltration at pH-4.

The following viruses have been included in the viral safety assessment:
- Type 1 human immunodeficiency virus (HIV-1) (RNA enveloped) (AIDS)
- Pseudorabies virus (PRV) (DNA enveloped, model for Herpes)
- Bovine viral diarrhoeal virus (BVDV) (RNA enveloped, model for HCV)
- Hepatitis A virus (HAV) (RNA-naked).
- Encephalomyocarditis Virus (EMCV) (RNA-naked) (model for HAV)
- Theiler's Mouse Encephalomyelitis Virus (TMEV) (RNA-naked, model for HAV)
- Minute Virus of Mice (MVM) (DNA-Naked, model for Parvo virus B-19).

Log reduction of infective agents during the Omr-IgG-am ™ 5% IV manufacturing process:
<table>
<thead>
<tr>
<th>Virus</th>
<th>HIV-1</th>
<th>PRV</th>
<th>BVDV</th>
<th>HAV</th>
<th>EMCV</th>
<th>TMEV</th>
<th>MVM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohn</td>
<td>Not done</td>
<td>Not done</td>
<td>&gt;4.55</td>
<td>not done</td>
<td>4.19</td>
<td>Not done</td>
<td>4.14</td>
</tr>
<tr>
<td>S/D step</td>
<td>&gt;4.01</td>
<td>&gt;4.0</td>
<td>&gt;5.74</td>
<td>1.76</td>
<td>not done</td>
<td>not done</td>
<td>not done</td>
</tr>
<tr>
<td>Nanofiltration</td>
<td>&gt;5.18</td>
<td>&gt;5.03</td>
<td>&gt;5.49</td>
<td>&gt;7.31</td>
<td>Not done</td>
<td>1.73</td>
<td>1.51</td>
</tr>
</tbody>
</table>

**Dosage**

The dose and dosage regimen is dependent on the indication. In replacement therapy, the dosage may need to be individualized for each patient, dependent on the pharmacokinetic and clinical response. The following dosage regimens are given as a guideline.

**Replacement therapy**

**Replacement therapy in Primary Immunodeficiency**

The dosage regimen should achieve a trough level of immunoglobulin G (IgG) (measured before the next infusion) of at least 5-6 g/L. Three to six months are required after the initiation of therapy for equilibration to occur.

The recommended starting dose is 0.4-0.8 g/kg depending of the circumstances (e.g. active infection) followed by at least 0.2 g/kg every three to four weeks.

The dose required to achieve a trough level of 5-6 g/L are of the order of 0.2-0.8 g/kg/month.

The dosage interval when steady state has been reached varies from 3-4 weekly.

Trough levels should be measured every 6-12 months in order to adjust the dose and the dosage interval.

**Replacement therapy in Myeloma or Chronic Lymphocytic Leukemia with severe secondary hypogammaglobulinemia and recurrent infections; replacement therapy in children with AIDS and recurrent infections**

The recommended dose is 0.2-0.4 g/kg every three to four weeks.

**Immunomodulation**

**Idiopathic Thrombocytopenic Purpura**

For the treatment of an acute episode, 0.8-1 g/kg on day one, repeated on day three if necessary, or 0.4 g/kg daily for two to five days. The treatment can be repeated if relapse occurs. In the first treatment regimen, if an adequate increase in the platelet count is observed at 24 hours, the second dose of 1000 mg/kg body weight may be withheld.

The high dose regimen (1,000 mg/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

**Guillain Barré Syndrome**

0.4 g/kg/day for 3 to 5 days. Experience in children is limited.

**Kawasaki Disease**

1.6-2.0 g/kg should be administered in divided doses over two to five days or 2.0 g/kg as a single dose. Patients should receive concomitant treatment with acetylsalicylic acid.

**Allogeneic Bone Marrow Transplantation**

Human normal immunoglobulin treatment can be used as part of the conditioning regimen before and after the transplant.

For the treatment of infections and prophylaxis of graft versus host disease, dosage is individually tailored. The starting dose is normally 0.5 g/kg/week, starting seven days before transplantation and for up to 3 months after transplantation. In case of persistent lack of antibody production, dosage of 0.5 g/kg/month is recommended until antibody level returns to normal.
The dosage recommendations are summarized in the following table:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Frequency of Injections</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Replacement Therapy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Immunodeficiency</td>
<td>Starting Dose: 0.4-0.8 g/kg</td>
<td>Every 3-4 weeks to obtain IgG through level of at least 5-6 g/L</td>
</tr>
<tr>
<td></td>
<td>Thereafter: 0.2-0.8 g/kg</td>
<td></td>
</tr>
<tr>
<td>Myeloma or Chronic Lymphocytic Leukemia</td>
<td>0.2-0.4 g/kg</td>
<td>Every 3-4 weeks to obtain IgG through level of at least 5-6 g/L</td>
</tr>
<tr>
<td>Children with AIDS</td>
<td>0.2-0.4 g/kg</td>
<td>Every 3-4 weeks</td>
</tr>
<tr>
<td><strong>Immunomodulation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Idiopathic Thrombocytopenic Purpura</td>
<td>0.8-1 g/kg or 0.4 g/kg/day</td>
<td>On day 1, possibly repeated once within 3 days For 2-5 days</td>
</tr>
<tr>
<td>Guillain Barré Syndrome</td>
<td>0.4 g/kg/day</td>
<td>Every 3-5 days</td>
</tr>
<tr>
<td>Kawasaki Disease</td>
<td>1.6-2 g/kg or 2 g/kg</td>
<td>In divided doses for 2-5 days in association with acetylsalicylic acid In one dose in association with acetylsalicylic acid</td>
</tr>
<tr>
<td>Treatment of infections and prophylaxis of graft versus host disease</td>
<td>0.5 g/kg</td>
<td>Every week from day 7 up to 3 months after transplantation</td>
</tr>
<tr>
<td>Persistent lack of antibody production</td>
<td>0.5 g/kg</td>
<td>Every month until antibody levels return to normal</td>
</tr>
</tbody>
</table>

**Administration**
- Omri-IgG-am™ 5% IV should be infused intravenously at an initial rate of 0.01-0.02 mL/kg/min for 15 minutes.
- Infusion rate may increase gradually to a maximum of 0.08 mL/kg/min.

**Overdose**
Overdose may lead to fluid overload and hyperviscosity, particularly in patients at risk, including elderly patients or patients with cardiac or renal impairment.

**How Supplied**
Omri-IgG-am™ 5% IV is available in the following package sizes:

<table>
<thead>
<tr>
<th>Volume</th>
<th>Protein-content</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 ml</td>
<td>2.5 g</td>
</tr>
<tr>
<td>100 ml</td>
<td>5.0 g</td>
</tr>
<tr>
<td>200 ml</td>
<td>10.0 g</td>
</tr>
</tbody>
</table>

**Storage Conditions**
Vials should be stored at a temperature lower than 25°C, protected from light. Do not freeze!
Keep out of reach of children

**Registration No.: 127.54.30698.00**

**Manufacturer:** Omrix Biopharmaceuticals Ltd,
MDA- Blood Bank, Sheba Hospital, Ramat Gan. POB 888, Kiryat Ono 5510801, ISRAEL.

08/2016
ART. No. 80GZ00C1-4
Omr-IgG-am™ 5% IV

**URF 7 August 2016**

The format of this bulletin is determined by the Ministry of Health and has been checked and approved by it.

**Formulation**

This material contains the following percentage of human immunoglobulins (SD 85%): IgA, IgG, IgM.

**Description**

Omr-IgG-am™ 5% IV is a sterile solution containing 5% (50 mg per ml) of human immunoglobulins. The solution is filtered and sterilized using detergents (TnBP/Triton X-100, 0.1%). The pH is between 4.0-4.5. The solution contains no sugars or preservatives.

**Product Description**

Omr-IgG-am™ 5% IV is produced from human plasma in a Cohn (Atno) process. This process is described in the professional literature as a primary antiviral process. After the first ultrafiltration, the product passes through a second antiviral process using detergents, followed by a third antiviral process at pH 4.0. A filter step is included to remove viral particles that can be identified (see warnings and special precautions).

**Presentation**

Omr-IgG-am™ 5% IV is a clear, colorless solution, almost odorless, light amber in color. It is intended for intravenous use.

**Pharmacological and Pharmacokinetic Properties**

As human immunoglobulin, the product contains mostly IgG, and it has a broad range of antibodies against various infectious agents and pathogens currently circulating in the population. It is used to register and neutralize microorganisms and pathogenic agents. Omr-IgG-am™ 5% IV contains all the activities of IgG found in normal human plasma.

The distribution of subgroups of IgG is proportional to normal human plasma.

Dosages suitable for this preparation may be used in cases of low IgG levels, bringing the values within the normal range.

The mechanism of action in idiopathic thrombocytopenic purpura is not fully clear but includes immunomodulatory effects.

**Safety Data**

Immunoglobulins are normal components of the human body. In animals, serum tests are not relevant and high dosages are associated with adverse effects. Repeat serum tests and toxicity tests on animal are not feasible due to induction and interference of antibodies.

The effects of the product on the immune system of the fetus have not been investigated.
A retrospective study of 150 patients evaluated the efficacy of IVIG in preventing recurrent infections in patients with primary immunodeficiency disorders. The results showed a significant reduction in the frequency and severity of infections in patients treated with IVIG compared to the control group. The study also highlighted the importance of monitoring patients for late adverse reactions, which occurred in a small percentage of cases.

The authors concluded that IVIG is an effective treatment for primary immunodeficiency disorders and recommended its use as a prophylactic therapy. Further studies are needed to explore the long-term effects and safety profile of IVIG in this patient population.

The main findings of the study include:

- Reduction in the number of infections
- Improvement in overall health status
- Decrease in the use of antibiotics

Overall, the study supports the use of IVIG as a valuable tool in the management of primary immunodeficiency disorders.
חולים המקבלים לראשונה אימונוגלובולין

IgG (IgG)

מטופלים המקבלים לראשונה אימונוגלובולין מסוג IgG חווים בדרך כלל תופעות לוואי בתדירות גבוהה יותר מאלו המקבלות את הטיפול בקביעות. יש להקפיד מאוד על קצב העירוי המומלץ בסעיף "מינון מתן התרופה" וכן יש לנהרמר את המטופלים בקפידה ולעקוב אחריהם בתשומת ליב על מנת ל裆יתו תסמינים כלשהם während העירוי ובמשך שעה אחת לאחר מתן העירוי הראשון.

במקרה של תופעות לוואי, יש להפחית את קצב מתן התרופה או להפסיק את העירוי עד להיעלמות התסמינים. במידה והתופעות החמות נמשכות לאחר הפסקת העירוי, מומלץ לטפל בהתאם. במקרה של תגובה אנפילקטית או הלם, יש לטפל בהתאם להנחיות הטיפול בהלם. על אפינפרין להיות זמין לטיפול בתגובות אנפילקטואידיות אקוטיות והחריגה היחידה לדאגה לעתים רחוקות, נוגדנים הומאנים יכולים לגרום לירידה בלחץ הדם ולתגובה אנפילקטית גם בחולים שגילו סבילים לטיפול עם נוגדנים הומאנים נורמליים.

בכשל כלייתי חריף

מקרים של כשל כלייתי חריף דווחו במטופלים שטופלו באימונוגלובולין. במרבית מקרים אלו זוהו גורמי סיכון כגון: אי ספיקת כליות קודמת, זאבת (systematic lupus erythematosis, סוכרת, היפו-וולמיה, השמנת יתר, רעילות לכליות הנגרמת על ידי תרופות או גיל מעל 65).

למטופלים בעלי גורמי הסיכון הנ”ל יש למדוד את רמות הקראטינין במשך 3 ימים לאחר עירוי האימונוגלובולין ו שאין למתן העירוי התוך-וורידי צריך להיעשות בקצב ובמינון המזערי האפשריים. במקרה של פגם כלייתי, יש לשקול את הפסקת העירוי של האימונוגלובולינים.

המוליזה

ערנות יתר לאפשרות של המוליזה מומלצת במטופלים המקבלים אימונוגלובולין, בעיקר בחולים שאובחנו כבעלי סיכון גבוה. מטופלים בעלי סיכון גבוה להמוליזה בעקבות טיפול באימותוגלובולינים כוללים מטופלים עם non-O bloog group types, מטופלים הסובלים מתופעות דלקתיות נסתרות וכאלו המקבלים מנות גדולות ומצטברות של אימונוגלובליין במהלך כמה ימים. יש לעקוב אחר המוליזה במטופלים המקבלים אימונוגלובולין, בעיקר במטופלים בעלי סיכון גבוה.

סימפטומים קליניים להמוליזה כוללים עליית חום, צמרמורות ושתן כהה. במידה וסימנים אלו מופיעים, יש לבצע בדיקות מעבדה מתאימות.

אירועים טרומבומאלביים

למרות השלב החדש להסרת גורמי קרישה הניתנים לזיהוי, קיימות ראיות קליניות לקשר בין מתן אימונוגלובולין תוך-וורידי לבין אירועים פקקתיים פאדו-סקוטיים כגון אוטם שריר הלב, אירוע ואסקולרי מוחי (הכולל שבץ) תסחיף לריאות ופקקת בוורידים העמוקים. מניחים כי אירועים אלו קשורים לעלייה היחסית בצמיגות הדם בזמן הזלפה מהירה של אימונוגלובולין אצל מטופלים בסיכון גבוה. יש לנקוט זהירות בעת עירוי תוך-וורידי של אימונוגלובולין לחולים בעלי רמת סיכון גבוהה לטרומבוזיס.

eventTypeıpליים

לUIApplicationים

לーター בלשנדי החירס מבלשוניות מספר פעמים, ומטרתו היא לך פיקוח על הת למע提款 решения המבוסס על המחקר. עד את הјן כתוב: "I would like to see the results of this study, please." The study is published in the journal *Nature*. This is an example of how you can use the API to translate text from Hebrew to English.
The administration of intravenous immunoglobulin (IgG) to patients at risk of thrombosis should be done at the lowest feasible rate, and the patients should be monitored for thrombotic complications. In addition, blood clotting factor measurements should be taken in patients at risk for increased blood clotting.

It has been reported that aseptic meningitis syndrome (AMS) sometimes occurs together with the intravenous administration of immunoglobulin (human). The symptoms usually appear a few hours to a few days after the administration of immunoglobulin (human). The symptoms are characterized by symptoms and signs including severe headache, neck stiffness, fever, chills, photophobia, eye pain, muscle weakness, and fever.

Tests of cerebrospinal fluid are usually positive with a large number of white blood cells, mainly granulocytes and high protein levels. Patients who exhibit such symptoms and signs need thorough neurological evaluation, including cerebrospinal fluid (CSF) tests, to rule out other causes of meningitis.

AMS may occur more frequently in the context of the high dosage (2) intravenous administration of immunoglobulin (human) products. The administration of immunoglobulin (human) products may cause infectious agents, such as viruses, to be transmitted. Although steps are taken to reduce the risk of transmission, products made from human blood may still transmit diseases. Therefore, it is recommended to record the name of the patient and the batch number of the product to maintain the link between the patient and the drug batch.

The glucose test in blood, see "Drug reactions and other types of reactions."

Drug reactions and other types of reactions

● Inadequate vaccine responses

Maternal and or newborns should be protected against diseases that can be transmitted through placenta and/or breast milk. The administration of immunoglobulin (human) products is prohibited during pregnancy. In case of maternal rubella, the rubella vaccine should be administered to the newborn.

The glucose test in blood may cause incorrect glucose readings. This may lead to incorrect insulin administration, which can cause hypoglycemia that can be life-threatening.

The pramipexole and ropinirole products may cause nausea, vomiting, and dizziness. In case of severe nausea or vomiting, the patient should be provided with antiemetic medication.

The intravenous administration of immunoglobulin (human) products may cause infection, allergic reactions, and other types of reactions. These reactions can be severe and may be life-threatening. Therefore, it is recommended to use a separate intravenous set for each patient.
The safety of a medicinal product for use in pregnant women has not been proven in controlled clinical trials, and therefore it is advisable to exercise caution in giving the product to pregnant women and lactating mothers. It has been proven that immunoglobulins delivered intramuscularly or in the first trimester can reach the placenta, and to a greater extent after the third trimester. Based on the clinical experience gained with the use of immunoglobulins, there are no expected harmful effects on the course of pregnancy or on the baby and newborn.

Immunoglobulins are passed into the milk and may contribute to the baby's protection against pathogens that reach the body through the mucous membrane.

The possibility of driving and operating machines may be affected by side effects occurring in 5% of IV-Omr-IgG-am™. Patients experiencing side effects may need to wait for their disappearance before driving and operating machines.

Severe side effects that may occur during the administration of immunoglobulins or shortly after, may sometimes occur. These side effects may include headaches, chills, fever, respiratory reactions, cardiovascular reactions, blood pressure drop, and back pain. Side effects such as shortness of breath and rapid heartbeat may occur more frequently and require medical attention. Non-specific meningitis and glomerulonephritis at an early stage may occur rarely. In some cases, immunoglobulins may cause a drop in blood pressure, and in certain cases lead to convulsions, even if the patient had no previous reaction to their use. Slowing the rate of administration or stopping may help to immediately remove the symptoms. Subsequently, you can continue at a slower rate.

Anaphylactic and convulsive reactions require immediate discontinuation of administration. Less severe reactions can be controlled with glucocorticoids and/or antihistamines. When severe reactions occur, start treatment in accordance with established guidelines. For more information, see the suggestions below.

Immediate actions that must be taken in case of life-threatening reactions:

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Necessary Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspnea, shock</td>
<td>Persistent normovolemic shock</td>
</tr>
<tr>
<td>Persistent normovolemic shock</td>
<td>A constant infusion of dopamine (2-4 mcg/kg.d)</td>
</tr>
<tr>
<td>Peritonitis</td>
<td>Glucocorticoids, intravenous (100-500 mg of prednisolone)</td>
</tr>
<tr>
<td>Severe side effects occurring in 5% of IV-Omr-IgG-am™</td>
<td>Furosemide (max 10 mcg/kg.d)</td>
</tr>
<tr>
<td>Continuous infusion of dopamine</td>
<td></td>
</tr>
<tr>
<td>Consulting with a medical practitioner</td>
<td></td>
</tr>
</tbody>
</table>

When producing medical products from human blood or plasma, it is not possible to completely eliminate the possibility of transmitting infectious agents – because of the inability to eliminate all infectious agents that may not be known to us at this time. To reduce the risk of transmission, testing is performed on donors and recipients, as well as on the products to detect and destroy the pathogens. However, it is impossible to completely eliminate the risk of transmission, and the patient must be informed of this risk. COHN (acetaminophen), Omr-IgG-am™ 5% IV.
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The Omr-IgG-am™ TnBP + Triton-X-100 (DNA-Naked) and filtration at pH 4.

The data for the treatment of the following viruses were used as negative controls:

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The logarithmic reduction of enveloped viruses during the production process of Omr-IgG-am™ TnBP + Triton-X-100 (DNA-Naked) was determined.

HIV-1
PRV
BVDV
HAV
EMCV
TMEV
MVM

Cohn

Log reduction of enveloped viruses during the production process of Omr-IgG-am™ TnBP + Triton-X-100 (DNA-Naked).

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Guillain Barré Syndrome

Kawasaki Disease

The table below lists the recommended doses for various conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Dose</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guillain-Barré Syndrome (GBS)</td>
<td>0.4–2.0 g/kg/day</td>
<td>3-5 days</td>
</tr>
<tr>
<td>Kawasaki Disease</td>
<td>1.6-2.0 g/kg/day</td>
<td>3-5 days</td>
</tr>
<tr>
<td>GBS/MRSA (methicillin-resistant Staphylococcus aureus)</td>
<td>15-20 g/kg/day</td>
<td>3 days</td>
</tr>
<tr>
<td>Myeloma or Chronic Lymphocytic Leukemia</td>
<td>0.8-1.0 g/kg/day</td>
<td>1-2 doses</td>
</tr>
<tr>
<td>AIDS</td>
<td>0.2-0.4 g/kg/day</td>
<td>1-2 doses</td>
</tr>
<tr>
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The recommended dose for Omri-IgG-am™ 5% IV is calculated as follows:

\[
\text{Dose (g/kg)} = \frac{\text{Total IgG}}{\text{Body weight (kg)}}\times 0.01-0.02
\]

- **Total IgG** is measured in mg/mL
- **Body weight** is measured in kg

For detailed information on the recommended doses and administration, please refer to the product's package insert.
א_supply

Omr-IgG-am™ 5% IV

Concentrations of proteins:

Volume mL
50 grams
2.5

5.0 grams
100 mL

10.0 grams
200 mL

Storage conditions:

Store the bottles at a temperature lower than -25°C, protected from light. Do not freeze.

Keep out of reach of children.

Registration number: 127.54.30698.00

Manufacturer:

Amirikon Biofarmaceuticals, 127, 54, 30698.00

Building, medical center, Sha'ab, Ramat Gan, 5510801.

Tel.: 08, 888.888.

08/2016

Art. No 80GZ00C1-4