100 mm

260 mm

FOR THE USE OF A REGISTERED MEDICAL PRACTITIONER OR A HOSPITAL ONLY
FOR SUBCUTANEOUS ADMINISTRATION ONLY

Globucel®- SC

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Manufactured from Human Plasma

NAME OF THE MEDICINAL PRODUCT
Globucel®–SC Human Normal Immunoglobulin I.P., 16.5% Solution
Supplied as 1 ml, 10 ml and 20 ml

QUALITATIVE AND QUANTITATIVE COMPOSITION
Globucel®–SC is Human normal immunoglobulin (SCIg), a sterile and solvent-detergent (S/D) treated preparation of highly purified Immunoglobulin G (IgG) intended for subcutaneous administration. It is prepared from the large pools of the human plasma obtained from the healthy donors. Globucel®–SC is used to provide passive immunity by increasing an individual's antibody titer and antigen-antibody reaction potential. Globucel®–SC also helps to prevent or modify certain infectious diseases in susceptible individuals.

Each vial contains:

Total Protein	165 g/L
Immunoglobulin G	≥ 90 %
Glycine (As stabilizer)	20 g/L
IgA Content	≤ 200 mg/L
IgG Subclass	Normal Distribution
Water for injection	q.s

Therapeutic indications
Replacement therapy in adults and children in primary immunodeficiency syndromes such as:
- Congenital agammaglobulinaemia and hypogammaglobulinaemia
- Common variable immunodeficiency (CVID)
- Severe combined immunodeficiency
- IgG subclass deficiencies with recurrent infections

Replacement therapy in myeloma or chronic lymphatic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections

Posology and method of administration

Posology
Replacement therapy
The treatment should be initiated and monitored under the supervision of a physician experienced in the treatment of immunodeficiency.
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 guidance.
The dosage regimen using the subcutaneous route should achieve a sustained level of IgG. A loading dose of at least 0.2-0.5 g/kg may be required. After steady state IgG levels have been attained, maintenance doses are administered at repeated intervals to reach a cumulative monthly dose of the order of 0.4-0.8 g/kg.
Trough levels should be measured in order to adjust the dose and dosage interval.

Method of administration
Globucel®–SC should be administered via the subcutaneous route. Do not use solution if gel or precipitate is observed.

Subcutaneous infusion for home treatment should be initiated by a physician experienced in the guidance of patients for home treatment. The patient will be instructed in the use of a syringe driver, infusion techniques, the keeping of a treatment diary and measures to be taken in case of severe adverse events.

Subcutaneous infusion with syringe driver
A common dose is 0.6 ml (100 mg) Globucel®–SC per kg body weight once a week, which may be administered at several infusion sites. Initial infusion rate: 10 ml/hour/syringe driver. The infusion rate may be gradually increased by 1 ml/hour/syringe driver every three to four weeks. The maximum dose administered has been 40 ml/hour using two syringe drivers simultaneously.
When large doses are given, it is advisable to administer them in divided doses at different sites.

Paediatric Patients
Data on children suffering from PID are available. As with adults, trough levels should be measured in order to adjust the dose and dosage interval. After steady state IgG levels have been attained, maintenance doses of about 80 to 100 mg/kg/week are usually administered to reach a cumulative monthly dose of the order of 0.4-0.8 g/kg. The proposed dosage regimen applies to all subsets of the paediatric population. If home treatment is considered, advice from a physician experienced in the guidance of patients for home treatment should be sought. The patient's parents should be instructed in the use of the application device, infusion techniques, the keeping of a treatment diary and measures to be taken in case of severe adverse events.

Contraindications Hypersensitivity to any of the components. Globucel®–SC must not be given intravenously.

Special warnings and precautions for use
If Globucel®–SC is accidentally administered into a blood vessel, patients could develop shock.
Patients should be closely monitored and carefully observed for any adverse events throughout the infusion period and for at least 20 minutes after the infusion.
Certain adverse reactions may occur more frequently in patients who receive human normal immunoglobulin for the first time or, in rare cases, when the human normal immunoglobulin product is switched or when treatment has been stopped for more than eight weeks.
True hypersensitivity reactions are rare. They can particularly occur in the very rare cases of IgA deficiency with anti-IgA antibodies and these patients should be treated with caution.
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.

Potential complications can often be avoided by ensuring that:
- Patients are not sensitive to human normal immunoglobulin, by first injecting the product slowly
- Patients are carefully monitored for any symptoms throughout the infusion period. In particular, patients naive to human normal immunoglobulin, patients switched from an alternative 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.

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment should be implemented.

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.
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 HAV and parvovirus B19.

There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.

It is strongly recommended that every time that Globucel®–SC is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.
Globucel®–SC does not protect against hepatitis A or measles.

Interaction with other medicinal products and other forms of interaction

Live attenuated virus 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 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
After injection of immunoglobulin the transitory rise of the various passively transferred antibodies in the patients' blood may result in misleading positive results in serological testing.
Passive transmission of antibodies to erythrocyte antigens, e.g. A, B, D may interfere with some serological tests (reticulocyte count, haptoglobin and Coombs test).

Pregnancy and lactation
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. 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.

Side effects
Injection site reaction, swelling, soreness, redness, induration, local heat, itching, bruising and rash are common side effects observed with human normal immunoglobulins. Rarely human normal immunoglobulins may cause a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

Pharmacodynamic properties
Human normal immunoglobulin contains mainly immunoglobulin G (IgG) with a broad spectrum of antibodies against infectious agents.
Human normal immunoglobulin contains the IgG antibodies present in the normal population. It is usually prepared from pooled plasma from not fewer than 1000 donations. It has a distribution of immunoglobulin G subclasses closely proportional to that in native human plasma. Adequate doses of this medicinal product may restore abnormally low immunoglobulin G levels to the normal range

List of excipients
Glycine

Incompatibilities
In the absence of compatibility studies, this medicinal product should not be mixed with other medicinal products.

Special precautions for disposal and other handling
The product should be brought to room or body temperature before use.
The solution should be clear or slightly opalescent and colourless. Do not use solutions that are cloudy or have deposits.
Any unused product or waste material should be disposed of in accordance with local requirements.

Shelf life
24 months from the manufacturing date.
Do not use after expiry date.

STORAGE CONDITION
Store between 2°C to 8°C. Store the vial in outer carton in order to protect from light.
Do not freeze.
Keep out of reach and sight of children.
Report suspected adverse reactions at:
Hemofluidsafety@intaspharma.com

Manufactured and Marketed by:
INTAS
INTAS PHARMACEUTICALS LTD.
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