

INTRADERMAL ADMINISTRATION OF IMMUNOGLOBULIN G PREPARATION

BACKGROUND

Field

[0001] The present disclosure is related to a method for administration of IgG preparations by the intradermal (ID) route to a patient in need thereof and a composition for administration of IgG preparations by the ID route to a patient.

Description of the Related Art

[0002] Immunoglobulin G (IgG) is the most abundant immunoglobulin isotype in human serum, comprising approximately 80% of all immunoglobulins. IgG preparations are indicated for the treatment of various diseases such as primary immunodeficiency, in particular congenital agammaglobulinaemia and hypogammaglobulinaemia, idiopathic thrombocytopenic purpura, as an adjuvant in the treatment of Kawasaki's Disease and in transplant of bone marrow, hypogammaglobulinaemia associated with chronic lymphocyte leukaemia as part of HIV infection treatment in pediatric patients, among others.

SUMMARY

[0003] In one aspect, the present invention refers to use of a composition comprising IgG in the manufacture of a medicament for the treatment of an immunodeficiency in a subject in need thereof by an intradermal (ID) route using a removable ID device comprising needles, wherein the IgG composition has an IgG concentration of 15% to 30% (w/v) and a pH of the IgG composition is from 4.5 to 8.0. In some examples, a method for administration of an IgG preparation by an intradermal (ID) route to a subject in need thereof is disclosed, the method comprising loading with a volume of the IgG preparation an ID delivery device comprising needles, applying the device to a skin delivery site, using the device to allow dermal penetration of the needles, delivering the volume of the IgG preparation at the skin delivery site, and removing the delivery device.

[0004] In some examples of the method, the IgG preparation has an IgG concentration of about 15% to about 30% (w/v). In some embodiments of the method, the IgG preparation has an IgG concentration of about 30% (w/v) or higher.

[0005] In some examples of the method, a pH of the IgG preparation is about 4.5 to about 8.0. In some examples of the method, the pH of the IgG preparation is about 6.5.

[0006] In some examples of the method, the volume of the IgG preparation is up to about 10 mL per skin delivery site. In some examples of the method, the volume of the IgG preparation is between about 2 mL and about 8 mL per skin delivery site. In some examples of the method, the volume of the IgG preparation is between about 4 mL and about 6 mL per skin delivery site.

[0007] In some examples of the method, the IgG preparation comprises one or more additional plasma proteins.

[0008] In some examples of the method, the subject is a pediatric patient. In some examples of the method, the subject is a non-pediatric patient.

[0009] In some examples, a composition comprising an IgG preparation for treatment of a disease in a subject in need thereof is provided.

[0010] In some examples of the composition, a concentration of IgG in the IgG preparation is about 15% to about 30% (w/v). In some examples of the composition, the concentration of IgG in the IgG preparation is about 30% (w/v) or higher.

[0011] In some examples, the composition has a pH of about 4.5 and about 8.0. In some examples of the composition, the pH is about 6.5.

[0012] In some examples of the composition, the subject is a pediatric patient. In some examples of the composition, the subject is a non-pediatric patient.

[0013] In some examples of the composition, the disease is an immunodeficiency. In some examples of the composition, the immunodeficiency is one of a primary immunodeficiency, a secondary immunodeficiency or an acquired immunodeficiency.

[0014] In some examples of the composition, the IgG preparation comprises an entire IgG molecule, a therapeutically effective fragment of IgG or a combination thereof.

[0015] In some examples of the composition, the IgG preparation comprises one or more additional plasma proteins.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] The present disclosure is described below in reference to the following figures.

[0017] FIG. 1 shows a line graph of plasma human IgG pharmacokinetics at 0-24 h in young farm pigs that were administered an IgG preparation (20 mg/kg) by the IV (n=4), SC (n=4) and ID (n=3) routes.

[0018] FIG. 2 shows a line graph of plasma human IgG pharmacokinetics at 0-240 h in young farm pigs that were administered an IgG preparation (20 mg/kg) by the IV (n=4), SC (n=4) and ID (n=3) routes

DETAILED DESCRIPTION

[0019] At present there is high demand for immunoglobulin G (IgG) which is polyvalent with a wide spectrum of human antibodies and has total functionality (neutralizing capacity, opsonization, half-life conserved), with intact molecules (integrity of the crystallizable Fc fragment) and a normal distribution of IgG subclasses identical or equivalent to natural plasma.

[0020] The usual routes for the therapeutic administration of IgG preparations include intravenous (IV), subcutaneous (SC) and intramuscular (IM). In addition, IgG may be administered by other routes such as the oral, nasal (inhaled) or topical routes. IV administration has become the standard approach for IgG supplementation in many countries, including the United States.

[0021] However, although IV administration offers the most useful therapeutic indications, for example, for the treatment of primary immunodeficiencies or for variable common immunodeficiency (deficit of IgG and IgA subclasses), secondary or acquired immunodeficiencies (for example infection by viruses such as cytomegalovirus, herpes zoster, human immunodeficiency) and diseases of an autoimmune origin (thrombocytopenic purpura, Kawasaki's Syndrome, for example), delivery of plasma-derived protein therapies

CLAIMS

1. Use of a composition comprising IgG in the manufacture of a medicament for the treatment of an immunodeficiency in a subject in need thereof by an intradermal (ID) route using a removable ID device comprising needles, wherein the IgG composition has an IgG concentration of 15% to 30% (w/v) and a pH of the IgG composition is from 4.5 to 8.0.
2. The use according to claim 1, wherein the pH of the IgG composition is 6.5.
3. The use according to claim 1, wherein the volume of the IgG composition is up to 10 mL per skin delivery site.
4. The use according to claim 3, wherein the volume of the IgG composition is between 2 mL and 8 mL per skin delivery site.
5. The use according to claim 3, wherein the volume of the IgG composition is between 4 mL and 6 mL per skin delivery site.
6. The use according to claim 1, wherein the IgG composition comprises one or more additional plasma proteins.
7. The use according to claim 1, wherein the subject is a pediatric patient.
8. The use according to claim 1, wherein the subject is a non-pediatric patient.