LIPIODOL® ULTRA-FLUID
Ethyl ester of iodized fatty acids of poppy seed oil

Lipiodol® efficacy & safety for tubal patency & uterine investigation 1,2,3,4,5,6

TUBAL FUSING

TUBAL IMAGING

UTERUS IMAGING

Guerbet
Contrast for Life

LIPIODOL® ULTRA-FLUID
Composition: Ethyl esters of iodized fatty acids of poppy seed oil 10 mL, corresponding to an iodine content of 480 mg/mL. Indications:**(*)

1. Hysterosalpingography: Assessing uterine patency. 2. Lipiodol® efficacy & safety. 3. Lipiodol® for tubal patency & uterine investigation. 4. Ethyl ester of iodized fatty acids of poppy seed oil - 10 mL glass ampoule, box of 1 - 10 mL glass ampoule, box of 50.

LIPIODOL® ULTRA-FLUID. Composition: Ethyl esters of iodized fatty acids of poppy seed oil 10 mL, corresponding to an iodine content of 480 mg/mL.

(*) For complete information please refer to the local Summary of Product Characteristics. For a copy of the SPC, please contact a member of Guerbet.

††† For complete information please refer to the local Summary of Product Characteristics.††† Indications, volumes and presentations may differ from country to country.

Overdosage (**)
The effects of overdose are not well known. The effects of overdose are not well known. Overdosage should not be treated with diuresis, dialysis, or other methods generally employed to treat overdosage of i.v. contrast media. Overdosage should not be treated with diuresis, dialysis, or other methods generally employed to treat overdosage of i.v. contrast media. Overdosage should not be treated with diuresis, dialysis, or other methods generally employed to treat overdosage of i.v. contrast media.

Countries in which HSG indication is registered: USA, Canada, UK, Ireland, The Netherlands, Denmark, Turkey, South-Africa, Japan, Taiwan, Thailand, Australia & New Zealand.

P17 067 LUF - October 2017 - Illustrations: Shutterstock

Revision: September 2, 2015.
Privigen® Immune Globulin Intravenous (Human), 10% Liquid

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Privigen does not contain sucrose.

For patients at risk of thrombosis, renal dysfunction or failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

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INDICATIONS AND USAGE

Privigen is an Immune Globulin Intravenous (Human), 10% Liquid indicated for the treatment of:

- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Primary humoral immunodeficiency (PI)

Privigen is made from human blood and may contain infectious agents, e.g., viruses, the variant Creutzfeldt Jakob disease [vCJD] agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

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ADVERSE REACTIONS

The most common adverse reactions, observed in >5% of study subjects, were:

- Headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute renal failure, blood pressure diastolic increased, hyponatremia, and increased body temperature.

Drug Interactions

The passive transfer of antibodies may:

- Lead to misinterpretation of the results of serological testing.
- Interfere with the response to live virus vaccines.

Use in Specific Populations

Geriatric: In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse Privigen at the minimum rate practicable.

See 17 for PATIENT COUNSELING INFORMATION.

Based on September 2017 revision
Privigen is the first and only IVIg formulated with proline for IgG stabilization

What is proline?
Proline is a naturally occurring amino acid, a critical component of human physiology, and a normal component of the human diet.

Features of proline stabilization
Proline stabilization offers:
- Reduced IgG aggregation
- Minimized fragmentation
- Reduced dimer formation
- Prevention of solution discoloration
- Room-temperature storage

Important Safety Information for Privigen

Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hyperprolinemia, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine.

Hyperproteinemia, increased serum viscosity, or hyponatremia can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion. Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Closely monitor patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimen for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Privigen is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common reactions, observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, increased diastolic blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient’s response to live virus vaccines and could lead to misinterpretation of serologic testing. In patients over 65 and those at risk of renal insufficiency, do not exceed recommended dose and infuse at the minimum rate practicable.

Please see accompanying brief summary of full prescribing information for Privigen.

References:
Proven protection
Designed for stability

Proven effective, Privigen is the first and only IVIg designed with proline stabilization

Important Safety Information
Privigen is indicated for the treatment of:

- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
  - Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin products, including Privigen. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

See full prescribing information for complete boxed warning.

Please see additional Important Safety Information and brief summary of full prescribing information for Privigen on accompanying pages.