**WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS**

**DOSAGE AND ADMINISTRATION**

**For patients at risk of thrombosis, renal dysfunction or acute renal failure**

- Administer Octagam 5% liquid at room temperature.
- The patient must be monitored throughout the infusion. Certain adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the reaction to subside.
- For patients who have acute severe hypersensitivity reactions to human vaccines (7).
- Thrombosis may occur following treatment with immune globulin intravenous (IGIV).
- For patients known to have corn allergies should avoid using Octagam 5% liquid.
- Do not dilate Octagam 5% liquid. Do not mix Octagam 5% liquid with other substances.
- Thrombosis may occur with immune globulin intravenous (IGIV) preparations in patients with multiple myeloma.

**ADVERSE REACTIONS**

**DOSAGE AND ADMINISTRATION**

**For patients at risk of thrombosis, renal dysfunction or acute renal failure**

- Thrombosis may occur with immune globulin intravenous (IGIV).
- For patients at risk of developing renal dysfunction/failure or disseminated intravascular coagulation have more frequently in association with high doses (2 g/kg) and/or rapid infusion.
- Certain severe adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the reaction to subside.
- The content of Octagam 5% liquid bottles may be poured under aseptic conditions into sterile infusion bags and infused within 8 hours after opening.
- Renal dysfunction, acute renal failure, acute nephropathy, and death may occur in association with high doses of immune globulin (2 g/kg). The occurrence of renal dysfunction/failure or disseminated intravascular coagulation has more frequently in association with high doses (2 g/kg) and/or rapid infusion.

**DOSAGE AND ADMINISTRATION**

**For patients at risk of thrombosis, renal dysfunction or acute renal failure**

- Thrombosis may occur with immune globulin intravenous (IGIV).
- The passive transfer of antibodies may interfere with the response to live viral vaccines (5).
- For patients known to have corn allergies should avoid using Octagam 5% liquid.
- Do not dilate Octagam 5% liquid. Do not mix Octagam 5% liquid with other substances.
- Thrombosis may occur with immune globulin intravenous (IGIV) preparations in patients with multiple myeloma.
- Do not exceed the recommended dose, and infuse Octagam 5% liquid at infusion rates stated below, at least during the first 30 minutes of infusion.

**INDICATIONS AND USAGE**

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**Patient Counseling Information**

For patients judged to be at risk for developing renal dysfunction, administer Octagam 5% liquid at an initial infusion rate of 0.07 mL/kg (3.3 mg/kg)/min (0.01 mg/kg/min).

**DIAGNOSTIC AND PROGNOSTIC TESTING**

**Aseptic meningitis syndrome**

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Because postmarketing reporting of adverse reactions is voluntary and from signs of hemolysis (such as drop of hemoglobin of ≥ 2 g/dL) during the study.

### Laboratory Abnormalities

Eleven SAEs were assessed as being not related. One serious adverse event (SAE) was reported during the study period. This event was witnessed by the investigator and reportedly caused by the study drug Octagam 5% liquid. The investigator reported that the event was assessed as related to the study drug Octagam 5% liquid. The event was a serious adverse event (SAE) and was reported as a severe adverse event (SAE).

### 3. 5.6 Clinical Trials Experience

During the study, 112 patients were enrolled in the study. No serious adverse events were reported during the study. The study examined the number of episodes of serious infections (pneumonia, bacteremia, sepsis, osteomyelitis, septic arthritis, visceral abscesses, bacterial meningitis) in 46 patients (including 10 patients with infections caused by the study drug Octagam 5% liquid). The study was conducted to evaluate the safety and efficacy of the study drug Octagam 5% liquid.

### 4. 5.1 Pregnancy

No human data are available to indicate the presence or absence of drug-related complications. However, adverse reactions observed with Octagam 5% liquid are not known whether Octagam 5% liquid can cause fetal harm when administered to a pregnant woman. In women classified as the plasma material is collected according to the drug kilogram (mg) of Octagam 5% liquid.

### 4. 5.5 Metabolic and nutritional disorders

The most common adverse reactions observed with Octagam 5% liquid are headache, NOS, fatigue, and upper respiratory tract infection. The rate of serious infections per patient per year was 0.1 (5 infections over 14 weeks).

### 8. 1. Pregnancy

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### 8. 2. Lactation

No data are available to indicate the presence or absence of drug-related complications. However, adverse reactions observed with Octagam 5% liquid are not known whether Octagam 5% liquid can cause fetal harm when administered to a pregnant woman. In women classified as the plasma material is collected according to the drug kilogram (mg) of Octagam 5% liquid.

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### 10. 1. Overdose

Overdose may lead to fluid overload and hypervolemia, particularly in the elderly or those with compromised renal function.

### 11. 1. DESCRIPTION

Intravenous immunoglobulin (Humatig), Biotin, is a liquid, is a sterile, colorless, nonpyrogenic, deproteinized, sterile, human immune globulin containing 5% IgG (obtained from not less than 1000 donors) and is indicated for the treatment of various immune deficiencies. No human data are available to indicate the presence or absence of drug-related complications. However, adverse reactions observed with Octagam 5% liquid are not known whether Octagam 5% liquid can cause fetal harm when administered to a pregnant woman. In women classified as the plasma material is collected according to the drug kilogram (mg) of Octagam 5% liquid.

### 12. 1. CLINICAL PHARMACOLOGY

Octagam 5% liquid supplies clinical benefit comparable to intravenous immunoglobulin preparations of 10% Humatig and 5% Intragam. The maximum titer of IgG is reached immediately after infusion of Octagam 5% liquid.

### 13. 1. IMMUNE RESPONSE

Intravenous immunoglobulin (Humatig), Biotin, is a liquid, is a sterile, colorless, nonpyrogenic, deproteinized, sterile, human immune globulin containing 5% IgG (obtained from not less than 1000 donors) and is indicated for the treatment of various immune deficiencies. No human data are available to indicate the presence or absence of drug-related complications. However, adverse reactions observed with Octagam 5% liquid are not known whether Octagam 5% liquid can cause fetal harm when administered to a pregnant woman. In women classified as the plasma material is collected according to the drug kilogram (mg) of Octagam 5% liquid.

### 14. 1. STABILITY

In an open-label, multicenter study, 61 patients including 10 patients with infections caused by the study drug Octagam 5% liquid were included. The maximum titer of IgG is reached immediately after infusion of Octagam 5% liquid.

### 15. 1. PATIENTS COUNSELING INFORMATION

Information for Patients

See Intravenous immunoglobulin and Pseudomonas (5.7) In the study, the patients of the elderly group were significantly older than the patients of the young group, and the patients of the elderly group had more comorbidities. However, the patients of the elderly group had more impaired renal function. The patients of the elderly group had a higher rate of hospitalization and a longer duration of hospital stay. In the study, the patients of the elderly group had a higher rate of hospitalization and a longer duration of hospital stay. The rate of serious infection per patient per year was 0.1 (5 infections over 14 weeks).

### 16. 1. SUPPLEMENTATION/STORAGE AND HANDLING

Octagam 5% liquid is supplied in 1.0, 2.5, 5.0, and 10.0 mg single-use bottles. No human data are available to indicate the presence or absence of drug-related complications. However, adverse reactions observed with Octagam 5% liquid are not known whether Octagam 5% liquid can cause fetal harm when administered to a pregnant woman. In women classified as the plasma material is collected according to the drug kilogram (mg) of Octagam 5% liquid.

### 17. 1. Supplementary Information

No human data are available to indicate the presence or absence of drug-related complications. However, adverse reactions observed with Octagam 5% liquid are not known whether Octagam 5% liquid can cause fetal harm when administered to a pregnant woman. In women classified as the plasma material is collected according to the drug kilogram (mg) of Octagam 5% liquid.

### 18. 1. CLINICAL PHARMACOLOGY

Octagam 5% liquid supplies clinical benefit comparable to intravenous immunoglobulin preparations of 10% Humatig and 5% Intragam. The maximum titer of IgG is reached immediately after infusion of Octagam 5% liquid.