DOSING AND ADMINISTRATION GUIDE

octagam® 5%

Immune Globulin
Intravenous (Human) 5%
Liquid Preparation

octagam® 10%

Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

Please see Full Prescribing Information, including BOXED WARNING, available at ***octa5hcp.com*** *and* ***octa10hcp.com.***

Pfizer Alternate Site | octapharma®

PREPARATION AND HANDLING

Indication and usage

OCTAGAM® 5% [Immune Globulin Intravenous (Human)] liquid is indicated for patients with primary humoral immunodeficiency (PI).

Available in 5 vial sizes to help meet the individual needs of your patients[1]

Size	1 g/20 mL	2.5 g/50 mL	5 g/100 mL	10 g/200 mL	25 g/500 mL
NDC	68982-840-01	68982-840-02	68982-840-03	68982-840-04	68982-840-05*

*Manufacturing site Octapharma Vienna only.

- The J Code for OCTAGAM 5% is J1568[2]

Ready-to-use liquid formulation[1]

- May be stored for 24 months at +2°C to +25°C (36°F to 77°F)

Selected Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 5% liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 5% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 5% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 5% liquid 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.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, available at octa5hcp.com.

octagam® 5%

Immune Globulin Intravenous (Human) 5% Liquid Preparation

PREPARATION AND HANDLING

The DOs and DON'Ts of OCTAGAM 5% [Immune Globulin Intravenous (Human)] liquid[1]

DO	DON'T
DO visually inspect OCTAGAM 5% for particulate matter and discoloration before using (if the solution and container permit).	**DON'T** use if OCTAGAM 5% is cloudy, opaque, not transparent, and/or discolored.
DO use right away after the bottle has been entered or opened, and throw away partially used bottles.	**DON'T** mix with other medicinal products or administer simultaneously with other intravenous preparation(s) in the same infusion set. **DON'T** mix with IgIV products from other manufacturers.
DO flush the infusion line before and after administration of OCTAGAM 5%, if needed, with either normal saline or 5% dextrose in water.	**DON'T** freeze OCTAGAM 5%. **DON'T** use OCTAGAM 5% if it has been frozen.
DO allow the solution to reach ambient room temperature prior to use.	**DON'T** use after the expiration date.
	DON'T dilute OCTAGAM 5%.

Administration of OCTAGAM 5%[1]

- OCTAGAM 5% should be used at room temperature. Only administer intravenously
- OCTAGAM 5% is not supplied with an infusion set. If an in-line filter is used, the pore size should be 0.2–200 microns
- Do not use a needle larger than 16 gauge to prevent the possibility of coring. Insert the needle only once, within the stopper area delineated (by the raised ring for penetration). The stopper should be penetrated perpendicular to the plane of the stopper within the ring
- Contents of OCTAGAM 5% bottles may be pooled under aseptic conditions into sterile infusion bags and infused within 8 hours after pooling

Drug interactions[1]

OCTAGAM 5% should not be mixed with other drugs or medications.

Selected Safety Information

OCTAGAM 5% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 5% liquid is contraindicated in patients with acute hypersensitivity reaction to corn. OCTAGAM 5% liquid contains maltose, a disaccharide sugar, which is derived from corn. Patients known to have corn allergies should avoid using OCTAGAM 5% liquid.

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

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 5% liquid with testing by some glucometers and test strip systems.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, available at octa5hcp.com.

octagam® 5%

Immune Globulin Intravenous (Human) 5% Liquid Preparation

RATE OF ADMINISTRATION

It is recommended that OCTAGAM 5% [Immune Globulin Intravenous (Human)] liquid be started at the infusion rates stated below, at least until the physician has had adequate experience with a given patient.[1]

Rate	mg/kg/min (mg/kg/hr)	mL/kg/min
First 30 minutes	0.5 (30)	0.01
Next 30 minutes, if above is tolerated	1 (60)	0.02
Next 30 minutes, if above is tolerated	2 (120)	0.04
Maximum	<3.33 (<200)	<0.07

See accompanying insert in pocket for the rate of administration by patient weight.

What to look out for[1]

- Monitor the patient carefully throughout the infusion. Certain adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the symptoms to disappear promptly
- Ensure that patients with pre-existing renal insufficiency are not volume-depleted
  –Discontinue OCTAGAM 5% if renal function deteriorates
- For patients at risk of renal dysfunction or thrombotic events, administer OCTAGAM 5% at the minimum infusion rate practicable

Selected Safety Information

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 5% liquid.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 5% liquid, especially with high doses or rapid infusion.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 5% liquid. Risk factors for hemolysis include high doses and non–O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 5% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, available at octa5hcp.com.

octagam® 5%

Immune Globulin
Intravenous (Human) 5%
Liquid Preparation

IMPORTANT SAFETY INFORMATION

Important Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 5% [Immune Globulin Intravenous (Human)] liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 5% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 5% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 5% liquid 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.

OCTAGAM 5% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 5% liquid is contraindicated in patients with acute hypersensitivity reaction to corn. OCTAGAM 5% liquid contains maltose, a disaccharide sugar, which is derived from corn. Patients known to have corn allergies should avoid using OCTAGAM 5% liquid.

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

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 5% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 5% liquid.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 5% liquid, especially with high doses or rapid infusion.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 5% liquid. Risk factors for hemolysis include high doses and non–O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 5% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

The most common adverse reactions reported in >5% of subjects during a clinical trial were headache and nausea. The most serious adverse reactions in treatment with OCTAGAM 5% liquid have been immediate anaphylactic reactions, aseptic meningitis, and hemolytic anemia.

Please see Full Prescribing Information, including BOXED WARNING, available at octa5hcp.com.

octagam® 5%

Immune Globulin
Intravenous (Human) 5%
Liquid Preparation

PRODUCT INFORMATION

Indication and usage

OCTAGAM® 10% [Immune Globulin Intravenous (Human)] liquid is indicated for adult patients with chronic immune thrombocytopenic purpura (ITP) to rapidly raise platelet counts to control or prevent bleeding.

Available in 4 vial sizes to help meet the individual needs of your patients[3]

Size	2 g/20 mL	5 g/50 mL	10 g/100 mL	20 g/200 mL
NDC	68982-850-01	68982-850-02	68982-850-03	68982-850-04

- The J Code for OCTAGAM 10% is J1568[2]

Ready-to-use liquid formulation[3]

- May be stored for 24 months at +2°C to +8°C (36°F to 46°F)
- May be stored up to 9 months at room temperature within the first 12 months of shelf life
- After storage at room temperature, the product must be used or discarded

Selected Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 10% liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 10% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 10% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 10% liquid 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.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, available at octa10hcp.com.

octagam® 10%

Immune Globulin Intravenous (Human) 10% Liquid Preparation

PREPARATION AND HANDLING

The DOs and DON'Ts of OCTAGAM 10% [Immune Globulin Intravenous (Human)] liquid[3]

DO	DON'T
DO visually inspect OCTAGAM 10% for particulate matter and discoloration before using (if the solution and container permit).	**DON'T** use if OCTAGAM 10% is cloudy, opaque, not transparent, and/or discolored.
DO use right away after the bottle has been entered or opened, and throw away partially used bottles.	**DON'T** mix with other medicinal products or administer simultaneously with other intravenous preparation(s) in the same infusion set. **DON'T** mix with IgIV products from other manufacturers.
DO flush the infusion line before and after administration of OCTAGAM 10%, if needed, with either normal saline or 5% dextrose in water.	**DON'T** freeze OCTAGAM 10%. **DON'T** use OCTAGAM 10% if it has been frozen.
DO allow the solution to reach ambient temperature prior to use, if it was previously stored at refrigerated temperatures.	**DON'T** use after the expiration date.
	DON'T dilute OCTAGAM 10%.

Administration of OCTAGAM 10%[3]

- OCTAGAM 10% should be used at room temperature. Only administer intravenously
- OCTAGAM 10% is not supplied with an infusion set. If an in-line filter is used, the pore size should be 0.2–200 microns
- Do not use a needle larger than 16 gauge to prevent the possibility of coring. Insert the needle only once, within the stopper area delineated (by the raised ring for penetration). The stopper should be penetrated perpendicular to the plane of the stopper within the ring
- Contents of OCTAGAM 10% bottles may be pooled under aseptic conditions into sterile infusion bags and infused within 8 hours after pooling

Drug interactions[3]

OCTAGAM 10% should not be mixed with other drugs or medications.

Selected Safety Information

OCTAGAM 10% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 10% liquid may cause hypersensitivity in patients with a corn allergy. OCTAGAM 10% liquid contains maltose, which is derived from corn.

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

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 10% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 10% liquid.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, available at octa10hcp.com.

octagam® 10%

Immune Globulin Intravenous (Human) 10% Liquid Preparation

RATE OF ADMINISTRATION

It is recommended that OCTAGAM 10% [Immune Globulin Intravenous (Human)] liquid be started at the infusion rates stated below, at least until the physician has had adequate experience with a given patient.[3]

Rate	mg/kg/min (mg/kg/hr)	mL/kg/min
First 30 minutes	1 (60)	0.01
Next 30 minutes, if above is tolerated	2 (120)	0.02
Next 30 minutes, if above is tolerated	4 (240)	0.04
Next 30 minutes, if above is tolerated	8 (480)	0.08
Maximum	≤12 (≤720)	≤0.12

See accompanying insert in pocket for the rate of administration by patient weight.

What to look out for[3]

- Monitor the patient carefully throughout the infusion. Certain adverse drug reactions may be related to the rate of infusion. Slowing or stopping the infusion usually allows the symptoms to disappear promptly. Once the symptoms subside, the infusion may then be resumed at a lower rate
- Ensure that patients with pre-existing renal insufficiency are not volume-depleted
  –Discontinue OCTAGAM 10% if renal function deteriorates
- For patients at risk of renal dysfunction or thrombotic events, administer OCTAGAM 10% at the minimum infusion rate practicable

Selected Safety Information

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 10% liquid. Risk factors for hemolysis include high doses and non–O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 10% liquid, especially with high doses or rapid infusion.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 10% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

The most common adverse reactions reported in >5% of subjects during a clinical trial were headache, fever, and increased heart rate. The most serious adverse reaction in treatment with OCTAGAM 10% liquid during a clinical trial was headache.

Please see additional Important Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, available at octa10hcp.com.

octagam® 10%

Immune Globulin Intravenous (Human) 10% Liquid Preparation

IMPORTANT SAFETY INFORMATION

Important Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 10% [Immune Globulin Intravenous (Human)] liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 10% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 10% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 10% liquid 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.

OCTAGAM 10% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 10% liquid may cause hypersensitivity in patients with a corn allergy. OCTAGAM 10% liquid contains maltose, which is derived from corn.

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

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 10% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 10% liquid.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 10% liquid. Risk factors for hemolysis include high doses and non–O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 10% liquid, especially with high doses or rapid infusion.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 10% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

The most common adverse reactions reported in >5% of subjects during a clinical trial were headache, fever, and increased heart rate. The most serious adverse reaction in treatment with OCTAGAM 10% liquid during a clinical trial was headache.

octagam® 10%

Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

Please see Full Prescribing Information, including BOXED WARNING, available at octa10hcp.com.

GETTING YOUR PATIENTS READY FOR TREATMENT

Here are a few tips to help get your patients ready for IgIV therapy

Before treatment

Drink plenty of liquids the day before and the day of treatment

Avoid caffeine and alcohol during this time—they can cause dehydration

Have enough reading materials or a TV nearby

During and after treatment

Tell your patients that their blood pressure and temperature will be checked during treatment

The infusion may take more than 2 hours

They should continue with normal activities following treatment

They should contact their healthcare provider if they have any questions or begin to experience any side effects

Please see Full Prescribing Information, including BOXED WARNING, available at octa5hcp.com and octa10hcp.com.

References: 1. OCTAGAM 5% [prescribing information]. Hoboken, NJ: Octapharma USA Inc; May 2018. **2.** HCPCS codes. Hcpcs.codes/j-codes/J1568. Accessed July 25, 2018. **3.** OCTAGAM 10% [prescribing information]. Hoboken, NJ: Octapharma USA Inc; May 2018. **4.** Data on file. Octapharma USA Inc.

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OCTAGAM® 5% [Immune Globulin Intravenous (Human)] liquid rate of administration by patient weight[1,4]

- For OCTAGAM 5%: 300 to 600 mg/kg every 3-4 weeks

Patient weight		mL/hr			
In kg	**In lb**	**First 30 minutes**	**Next 30 minutes** *(if previous rate tolerated)*	**Next 30 minutes** *(if previous rate tolerated)*	**Maximum** *(if previous rate tolerated)*
5	11	3	6	12	<20
10	22	6	12	24	<40
15	33	9	18	36	<60
20	44	12	24	48	<80
25	55	15	30	60	<100
30	66	18	36	72	<120
35	77	21	42	84	<140
40	88	24	48	96	<160
45	99	27	54	108	<180
50	110	30	60	120	<200
55	121	33	66	132	<220
60	132	36	72	144	<240
65	143	39	78	156	<260
70	154	42	84	168	<280
75	165	45	90	180	<300
80	176	48	96	192	<320
85	187	51	102	204	<340
90	198	54	108	216	<360
95	209	57	114	228	<380
100	220	60	120	240	<400
105	231	63	126	252	<420
110	242	66	132	264	<440
115	253	69	138	276	<460
120	264	72	144	288	<480
125	275	75	150	300	<500

For patients judged to be at risk for developing renal dysfunction or thromboembolic events, administer OCTAGAM 5% at the minimum infusion rate practicable, not to exceed 0.07 mL/kg (3.33 mg/kg/min)—equal to 4.0 mL/kg (200 mg/kg/hr).

Indication and usage

OCTAGAM® 5% [Immune Globulin Intravenous (Human)] liquid is indicated for patients with primary humoral immunodeficiency (PI).

Important Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 5% liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 5% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 5% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 5% liquid 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.

OCTAGAM 5% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 5% liquid is contraindicated in patients with acute hypersensitivity reaction to corn. OCTAGAM 5% liquid contains maltose, a disaccharide sugar, which is derived from corn. Patients known to have corn allergies should avoid using OCTAGAM 5% liquid.

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

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 5% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 5% liquid.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 5% liquid, especially with high doses or rapid infusion.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 5% liquid. Risk factors for hemolysis include high doses and non–O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 5% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

The most common adverse reactions reported in >5% of subjects during a clinical trial were headache and nausea. The most serious adverse reactions in treatment with OCTAGAM 5% liquid have been immediate anaphylactic reactions, aseptic meningitis, and hemolytic anemia.

Please see Full Prescribing Information, including BOXED WARNING, available at octa5hcp.com.

octagam® 5%

Immune Globulin Intravenous (Human) 5% Liquid Preparation

OCTAGAM® 10% [Immune Globulin Intravenous (Human)] liquid rate of administration by patient weight[3,4]

- For OCTAGAM 10%: 1 g/kg daily for 2 consecutive days

Patient weight		mL/hr				
In kg	In lb	First 30 minutes	Next 30 minutes *(if tolerated)*	Next 30 minutes *(if previous rate tolerated)*	Next 30 minutes *(if previous rate tolerated)*	Maximum *(if previous rate tolerated)*
40	88	24	48	96	192	≤288
45	99	27	54	108	216	≤324
50	110	30	60	120	240	≤360
55	121	33	66	132	264	≤396
60	132	36	72	144	288	≤432
65	143	39	78	156	312	≤468
70	154	42	84	168	336	≤504
75	165	45	90	180	360	≤540
80	176	48	96	192	384	≤576
85	187	51	102	204	408	≤612
90	198	54	108	216	432	≤648
95	209	57	114	228	456	≤684
100	220	60	120	240	480	≤720
105	231	63	126	252	504	≤756
110	242	66	132	264	528	≤792
115	253	69	138	276	552	≤828
120	264	72	144	288	576	≤864
125	275	75	150	300	600	≤900

For patients judged to be at risk for developing renal dysfunction or thromboembolic events, administer OCTAGAM 10% at the minimum infusion rate practicable, not to exceed 0.03 mL/kg (3.33 mg/kg/min)—equal to 2.0 mL/kg (200 mg/kg/hr).

Indication and usage

OCTAGAM® 10% [Immune Globulin Intravenous (Human)] liquid is indicated for adult patients with chronic immune thrombocytopenic purpura (ITP) to rapidly raise platelet counts to control or prevent bleeding.

Important Safety Information

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 10% liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 10% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 10% liquid does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 10% liquid 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.

OCTAGAM 10% liquid is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

OCTAGAM 10% liquid may cause hypersensitivity in patients with a corn allergy. OCTAGAM 10% liquid contains maltose, which is derived from corn.

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

Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 10% liquid with testing by some glucometers and test strip systems.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving OCTAGAM 10% liquid.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to treatment with OCTAGAM 10% liquid. Risk factors for hemolysis include high doses and non–O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Aseptic meningitis syndrome may occur in patients receiving OCTAGAM 10% liquid, especially with high doses or rapid infusion.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

OCTAGAM 10% liquid is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

The most common adverse reactions reported in >5% of subjects during a clinical trial were headache, fever, and increased heart rate. The most serious adverse reaction in treatment with OCTAGAM 10% liquid during a clinical trial was headache.

Please see Full Prescribing Information, including BOXED WARNING, available at octa10hcp.com.

octagam® 10%
Immune Globulin Intravenous (Human) 10% Liquid Preparation