MALTOSE FACTS

A Guide for Healthcare Professionals Using
Intravenous Immune Globulin (IVIG) &
Subcutaneous Immune Globulin (SCIg)

octapharma

MALTOSE FACTS

Maltose[1-8]

Maltose and other sugars such as icodextrin, galactose, and xylose may be found in some biologic therapies and other products (*see Table 1*). In addition, stabilizers used in IVIG or SCIG products include sugars such as glucose, maltose, d-sorbitol and sucrose, or amino acids such as glycine and proline. Octagam® and cutaquig® use maltose and contain no sucrose or preservatives. Currently all IVIG products contain a Boxed Warning regarding the potential for adverse renal effects (*see below*).

- When maltose is infused in normal or diabetic human subjects, it does not lead to elevated glucose levels
- When infused into a patient, maltose behaves very differently as compared to glucose or sucrose. This is because maltase, the enzyme that hydrolyzes maltose to glucose, is present in the brush border of the proximal convoluted renal tubules. Animal studies have demonstrated that while greater than 60% of sucrose is excreted unchanged in the urine, maltose is mostly metabolized with <5% excreted unchanged
- All IVIG products have the potential to cause nephrotoxicity in patients that have underlying renal disease and/or take concurrent nephrotoxic drugs, although as stated in the Boxed Warning, the risk is significantly higher with products containing sucrose. As of 2022, there are currently no sucrose-containing IVIG products available in the US market
- The incidence of renal impairment from IVIG use was reported in a retrospective analysis in 2013. This publication reports the results compiled from a search of the Medline and Embase databases for published data on adverse drug reactions (ADRs) involving the kidneys as well as DrugCite, a public database of >4,000,000 ADRs from the USA. The results suggest that compared with sucrose-containing IVIGs, reports of ADRs involving the kidneys were relatively rare with sucrose-free IVIGs

Maltose and Blood Glucose Monitoring Systems[1,2]

Certain blood glucose monitoring systems (BGMSs) falsely interpret maltose, icodextrin, galactose, and xylose as glucose and can potentially result in falsely elevated glucose readings. If insulin is administered as a result of these false readings, hypoglycemia can occur. The BGMSs that utilize test strips containing glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ) and glucose-dye-oxidoreductase (GDO) can result in this interference. This interference is not limited to maltose.

Octagam® 5% and Octagam® 10%

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

Please see octagam® 5% and octagam®10% full Prescribing Information for complete Boxed Warnings and additional important information.

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including octagam 5% and 10% liquid preparations. 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 in predisposed patients with IGIV products, including octagam 5% and 10% liquid preparations. Renal dysfunction and acute renal failure occur more commonly with IGIV products containing sucrose. Octagam 5% and 10% liquid preparations do not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure administer octagam 5% or 10% liquid preparations 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 accompanying full Prescribing Information for additional important information.

Products Exhibiting Interference With Some BGMSs

Table 1. Description of products and substances containing maltose, icodextrin, galactose, or xylose[1,2]

SUBSTANCE*	USE	COMMENTS
Bexxar®		Contains maltose
HepaGam B®		Contains maltose
Orencia®		Contains maltose
Vaccinia Immune Globulin®		Contains maltose
WinRho SDF®		Contains maltose
Icodextrin		Icodextrin is metabolized to maltose
Galactose		Promoted in health food stores for a wide range of illnesses and promoted as safe for use in diabetic patients
Xylose		Promoted in health food stores for a wide range of illnesses and promoted as safe for use in diabetic patients
Octagam® [Immune Globulin Intravenous (Human)] 5% liquid preparation		Contains maltose (100 mg maltose/mL in 50 mg IgG/mL [ie, 2 g maltose per 1 g IgG/Octagam®])
Octagam® [Immune Globulin Intravenous (Human)] 10% liquid preparation		Contains maltose (90 mg maltose/mL in 100 mg IgG/mL [ie, 0.9 g maltose per 1 g IgG/Octagam®])
Cutaquig® [Immune Globulin Subcutaneous (Human) - hipp], 16.5% solution		Contains maltose (79 mg/mL), but no preservatives or sucrose

Table 1 is a noncomprehensive list; substances and uses are current as of October 2022.
*Refer to manufacturer's product prescribing information for additional information.

How to Prevent This Interference[2]

- The FDA recommends that clinicians avoid using GDH-PQQ glucose test strips in healthcare facilities. Or if the facility currently uses GDH-PQQ glucose test strips, they should *never* be used on patients who are receiving interfering products, or on patients where it is not known if they are using interfering products
- Consult the package inserts for BGMSs and products containing maltose, icodextrin, galactose, or xylose, and educate patients and clinicians regarding this interference
- Screen ALL diabetic patients who are using the glucometers listed in Table 2 for the use of maltose-containing products, icodextrin, galactose, and xylose

FDA = US Food and Drug Administration; IgG = immunoglobulin G.

Cutaquig®

WARNING: THROMBOSIS

See full prescribing information for complete boxed warning

- Thrombosis may occur with immune globulin products, including cutaquig. 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.
- For patients at risk of thrombosis, administer cutaquig 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 of hyperviscosity.

Blood Glucose Monitoring Systems That CAN Be Used on Patients Receiving Products Containing Maltose, Icodextrin, Galactose, or Xylose[9,10]

Table 2.

MANUFACTURER & GLUCOMETER	ENZYME UTILIZED IN TEST STRIPS
Abbott Diabetes Care (Alameda, CA)	
Boots	GDH-NAD
FreeStyle Flash	GDH-NAD
FreeStyle Freedom	GDH-NAD
FreeStyle Freedom Lite	GDH-NAD
FreeStyle InsuLinx	GDH-FAD
FreeStyle Lite	GDH-NAD
FreeStyle Mini	GDH-NAD
FreeStyle Optium	GDH-NAD
FreeStyle Optium H	GDH-NAD
FreeStyle Optium Neo	GDH-NAD
FreeStyle Optium Neo H	GDH-NAD
FreeStyle Papillon InsuLinx	GDH-FAD
FreeStyle Papillon Lite	GDH-NAD
FreeStyle Papillon Mini	GDH-NAD
FreeStyle Papillon Vision	GDH-NAD
FreeStyle Precision	GDH-NAD
FreeStyle Precision H	GDH-NAD
FreeStyle Precision Neo	GDH-NAD
FreeStyle Precision Pro	GDH-NAD
Omron HEA-214	GDH-NAD
Optium	GDH-NAD
Optium Easy	GDH-NAD
OptiumEZ	GDH-NAD
Optium Xceed	GDH-NAD
Optium Xido	GDH-NAD
Optium Xido Neo	GDH-NAD
Precision Xceed	GDH-NAD

MANUFACTURER & GLUCOMETER	ENZYME UTILIZED IN TEST STRIPS
Abbott Diabetes Care *(continued)*	
Precision Xceed Pro	GDH-NAD
Precision Xtra	GDH-NAD
Precision Xtra OK*	GDH-NAD, GO
ReliOn Ultima	GDH-NAD
TrueSense	GDH-NAD
AgaMatrix, Inc. (Salem, NH)	
iBGST	GO
Jazz	GO
Jazz Wireless	GO
Presto	GO
Arkray, Inc. (Edina, MN)	
Assure Platinum	GO
Assure Prism	GO
GLUCOCARD 01	GO
GLUCOCARD 01-mini	GO
GLUCOCARD 01-mini plus	GO
GLUCOCARD Expression	GO
GlucoCard G Black	GDH-FAD
GlucoCard MX	GDH-FAD
GLUCOCARD MyDIA	GO
GlucoCard Prism†	GO
GlucoCard S	GDH-FAD
GlucoCard Shine	GO
GLUCOCARD Σ	GO
GLUCOCARD Σ-mini	GO
GlucoCard SM	GDH-FAD

*Two types of **compatible** test strips for Precision Xtra OK.
†This/These monitor/test strips were not currently certified as having been tested to Baxter's recommended interference limits for maltose or icodextrin when this list was issued. Consult manufacturer for additional information.

Important Information

This is a noncomprehensive list, current as of October 2022. Absence of a specific glucose monitor or test strips from this list does NOT imply compatibility or incompatibility with products that contain maltose, icodextrin, galactose, or xylose. Similarly, other glucose-measuring technologies that are not listed (such as continuous glucose monitoring systems) may or may not be compatible with these solutions.

Please see accompanying full Prescribing Information for additional important information.

MANUFACTURER & GLUCOMETER	ENZYME UTILIZED IN TEST STRIPS
Arkray, Inc. *(continued)*	
GLUCOCARD X-meter‡	GDH-FAD
GLUCOCARD X-mini‡	GDH-FAD
GLUCOCARD X-mini plus‡	GDH-FAD
GLUCOCARD Vital	GO
ReliOn Confirm	GO
ReliOn Micro	GO
ReliOn Prime	GO
Ascensia Diabetes Care (formerly Bayer Healthcare, Basel, Switzerland)	
Ascensia Brio	GO
Ascensia Entrust	GO
Breeze 2	GO
Contour	GDH-FAD
Contour Link	GDH-FAD
Contour Next	GDH-FAD
Contour Next EZ	GDH-FAD
Contour Next Link	GDH-FAD
Contour Next Link 2.4	GDH-FAD
Contour Next USB	GDH-FAD
Contour Plus	GDH-FAD
Contour TS	GDH-FAD
Contour USB	GDH-FAD
Contour XT	GDH-FAD
Elite§	GO
Elite XL	GO

MANUFACTURER & GLUCOMETER	ENZYME UTILIZED IN TEST STRIPS
LifeScan, Inc. (Milpitas, CA)	
OneTouch InDuo	GO
OneTouch Ping	GO
OneTouch Select	GO
OneTouch Select Mini	GO
OneTouch SelectPlus	GO
OneTouch SelectPlus Flex	GO
OneTouch Select Simple	GO
OneTouch SureStep	GO
OneTouch Ultra‖	GO
OneTouch Ultra 2	GO
OneTouch UltraEasy	GO
OneTouch UltraLink	GO
OneTouch UltraMini	GO
OneTouch UltraSmart	GO
OneTouch UltraVue	GO
OneTouch Verio	GDH-FAD
OneTouch VerioFlex	GDH-FAD
OneTouch VerioIQ	GDH-FAD
OneTouch VerioPro	GDH-FAD
OneTouch VerioPro+	GDH-FAD
OneTouch VerioSync	GDH-FAD
OneTouch VerioVue	GDH-FAD
OneTouch Vita	GO
SureStep Flexx	GO

GDH-FAD = glucose dehydrogenase flavin adenine dinucleotide; GDH-NAD = glucose dehydrogenase nicotine adenine dinucleotide; GO = glucose oxidase; Mut Q-GDH = glucose dehydrogenase with pyrroloquinoline quinone modified to eliminate maltose interference.

‡These Arkray monitors/test strips have switched from an **incompatible** GDH-FAD–based chemistry to a **compatible** GDH-FAD–based chemistry. Consult manufacturer for additional information.
§Baxter report REP-NIV-RE-366 Evaluation of potential interference in blood glucose determination (measured with enzymatic methods) for patients treated with icodextrin.
‖Baxter report Interim 1, 33541 Determination of potential interference of icodextrin and its metabolites on human blood glucose measurement using chosen glucometers.

Always contact the device manufacturer for current information. If the manufacturer cannot provide information regarding compatibility of the device with solutions containing maltose, icodextrin, galactose, or xylose, it is NOT recommended that patients use the product. Octapharma reserves the right to change this list without notice and does not represent that it includes all compatible or potentially incompatible products. While efforts have been made to provide accurate and current information, Octapharma does not manufacture these glucose monitors or test strips and thus does not guarantee the initial or continued accuracy of this information. Please contact the manufacturer(s) of the glucose monitor and test strip to obtain the latest compatibility information.

Blood Glucose Monitoring Systems That CAN Be Used on Patients Receiving Products Containing Maltose, Icodextrin, Galactose, or Xylose[9,10] *(continued)*

Table 2. *(continued)*

MANUFACTURER & GLUCOMETER	ENZYME UTILIZED IN TEST STRIPS
Nova Biomedical (Waltham, MA)	
Nova Max Link	GO
Nova Max Plus	GO
Nova Pro Glucose/Ketone Meter	GDG-FAD
StatStrip Hospital Glucose Meter	GO
StatStrip Hospital Glucose and Ketone Monitoring System	GO
StatStrip Xpress	GO
StatStrip Xpress Glucose and Ketone Monitoring System	GO
Prodigy Diabetes Care (Charlotte, NC)	
Prodigy AutoCode*	GO
Prodigy No Coding Test Strips*	GO
Prodigy Pocket*	GO
Prodigy Voice*	GO
Roche Diagnostics (Basel, Switzerland)	
Accu-Chek Active	Mut Q-GDH
Accu-Chek Aviva	Mut Q-GDH
Accu-Chek Aviva Combo	Mut Q-GDH
Accu-Chek Aviva Compact Plus	Mut Q-GDH
Accu-Chek Aviva Connect	Mut Q-GDH
Accu-Chek Aviva Expert	Mut Q-GDH
Accu-Chek Aviva Insight	Mut Q-GDH

GLUCOMETER	ENZYME UTILIZED IN TEST STRIPS
Roche Diagnostics (continued)	
Accu-Chek Aviva Nano	GDH-NAD
Accu-Check Aviva Plus†	GDH-NAD
Accu-Chek Inform II	GDH-NAD, GO
Accu-Chek Mobile	GDH-NAD
Accu-Chek Nano†	GDH-NAD
Accu-Chek Nano SmartView†	GO
Accu-Chek Performa	GO
Accu-Chek Performa Combo	GO
Accu-Chek Performa Connect	GO
Accu-Chek Performa Insight	GO
Accu-Chek Performa Nano	GO
Accu-Chek Voicemate Plus System	GO
Trividia Health (formerly Nipro Diagnostics, Inc., Fort Lauderdale, FL)	
TRUE METRIX-Pro	GO
TRUE METRIX-Air	GDH-FAD
TRUE METRIX-Go	GDH-FAD

*This/These monitor/test strips were not currently certified as having been tested to Baxter's recommended interference limits for maltose or icodextrin when this list was issued. Consult manufacturer for additional information.

†The Accu-Chek Nano (not Aviva or Performa) and Accu-Chek Aviva Plus glucose systems are available within the United States ONLY, and use test strips branded as Accu-Chek Smartview and Accu-Chek Aviva Plus, respectively. These systems use the Mut Q-GDH (**compatible**) strips. Consult manufacturer for additional information.

Important Information

This is a noncomprehensive list, current as of October 2022. Absence of a specific glucose monitor or test strips from this list does NOT imply compatibility or incompatibility with products that contain maltose, icodextrin, galactose, or xylose. Similarly, other glucose-measuring technologies that are not listed (such as continuous glucose monitoring systems) may or may not be compatible with these solutions.

Please see accompanying full Prescribing Information for additional important information.

Important Information
It is the responsibility of clinicians and patients to review the package insert of all test strips to determine the type of glucose testing system that is used, and use only those systems that utilize the glucose oxidase (GO), glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose dehydrogenase flavin adenine dinucleotide (GDH-FAD), or the glucose dehydrogenase with pyrroloquinoline quinone modified to eliminate maltose interference (Mut Q-GDH) methods of enzymes in their test strips when receiving products that contain maltose, icodextrin, galactose, or xylose. Blood glucose monitoring systems that cause falsely elevated glucose reading in the presence of maltose, icodextrin, galactose, or xylose are those systems that utilize the GDH-PQQ or GDO enzymes in their test strips.

This list is compiled from a search via: Internet, literature, Baxter internal studies, information from government agencies, test strip leaflets, safety alerts, and direct information from the product manufacturers. While efforts have been made to provide accurate and current information, Octapharma does not manufacture these glucose monitors or test strips and thus does not guarantee the initial or continued accuracy of this information. Please contact the manufacturer(s) of the glucose monitor and test strip to obtain the latest compatibility information.

Always contact the device manufacturer for current information. If the manufacturer cannot provide information regarding compatibility of the device with solutions containing maltose, icodextrin, galactose, or xylose, it is NOT recommended that patients use the product. Octapharma reserves the right to change this list without notice and does not represent that it includes all compatible or potentially incompatible products. While efforts have been made to provide accurate and current information, Octapharma does not manufacture these glucose monitors or test strips and thus does not guarantee the initial or continued accuracy of this information. Please contact the manufacturer(s) of the glucose monitor and test strip to obtain the latest compatibility information.

Contact Octapharma:

Octapharma USA, Inc.
117 W. Century Road
Paramus, NJ 07652
Tel: 201-604-1130

IgCares/Reimbursement Assistance
usreimbursement@octapharma.com
Tel: 800-554-4440

Medical Affairs
usmedicalaffairs@octapharma.com

For all inquiries relating to drug safety, or to report adverse events, please contact our local Drug Safety Officer:
Tel: 201-604-1137 | Cell: 201-772-4546 | Fax: 201-604-1141 or contact the FDA at 1-800-FDA-1088
or www.fda.gov/medwatch.

Connect:

www.octapharmausa.com www.octagamusa.com www.cutaquigusa.com

The IgCares Patient Support Program
Register at IgCares.com

References: 1. Data on file. Blood glucose monitoring systems (BGMSs) and Sugar interference. Octapharma, Inc. **2.** NS Medical Devices. FDA warns of potentially fatal errors with GDH-PQQ glucose monitoring technology. August 13, 2009. https://www.nsmedicaldevices.com/news/fda_warns_of_potentially_fatal_errors_with_gdhpqq_glucose_monitoring_technology_090813/ **3.** Schleis T. Pharmacotherapy. 2007;27:1313-1321. **4.** Young JM, Weser E. J Clin Invest. 1971;50:986-991. **5.** Toyota T, et al. Tohoku J Exp Med. 1974;114:61-69. **6.** Weser E, Sleisenger MH. J Clin Invest. 1967;46:499–505. **7.** Tahara Y, Fukuda M, Yamamoto Y, et al. Am J Clin Nutr. 1990;52:986-981. **8.** Dantal J. Am J Nephrol. 2013;38:275-284. **9.** Baxter International Inc. Country-specific glucose monitoring list. December 2020. https://www.glucosesafety.com/us/pdf/2020-12-17-CSGML_USA_2020.pdf **10.** Baxter International Inc. Country-specific glucose monitoring list. December 2017. https://www.glucosesafety.com/us/pdf/Glucose_Monitor_List_US_Dec2017.pdf

Please see accompanying full Prescribing Information for additional important information.

Date of preparation: 10/2022. CUTA-0795-PSA

octapharma