

Plasma Protein Products Transition

March 2018

NEWS

Immune globulins (Ig)

Updated Ig comparison tables are available at www.blood.ca in the plasma protein products section (see Hospitals/Products/Plasma Protein Products). Copies are attached at the end of this newsletter.

The Canadian Immunodeficiencies Patient Organization has arranged local meetings across Canada in March and April to provide an opportunity for patients to ask questions and raise concerns. Canadian Blood Services is a key participant in these meetings.

Hemophilia

Hemophilia clinics have been requested to provide Canadian Blood Services with the anticipated volumes of Eloctate and Alprolix they will require in the coming months. This utilization data will assist with managing the remaining demand for these two products.

Transition support

Canadian Blood Services will continue to provide updates on product ordering, current national inventory levels and other relevant information in this newsletter. Please see page 2 for timelines of product availability. Canadian Blood Services continues to work closely with all internal and external stakeholders to ensure a smooth transition.

National inventory

Please see page 3 for an update on impacted products in our inventory. Limited quantities of discontinued products will be available during the transition. A more detailed inventory summary, by vial size and by Canadian Blood Services site, will be shared directly with hospital and clinic customers via Canadian Blood Services' hospital liaison specialist network.

Ordering products

If your order exceeds a typical one-month supply, please submit it at least one week before the needed delivery date. This will allow sufficient time to ensure proper levels of product by SKU are available where and when needed. Order forms can be found at www.blood.ca.



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CHANGES

- Phase out timelines for some products have been revised. Refer to page 2 for updated information.
- Refer to page 3 for Canadian Blood Services' inventory snapshot as of March 2018.

Reminders:

- Shire will provide transition support for both Cuvitru and Adynovate as part of its OnePath Support Program. This support will consist of:
 - Training on the clinical features of the products.
 - Patient education materials.
 - Patient support for those receiving subcutaneous Ig treatment, including provision of ancillary supplies, reimbursement support and nurse training.
- Eloctate will be available for patients within their initial 50 to 100 exposure days, patients currently receiving immune tolerance induction (ITI) treatment, and children under 12 years of age, until Adynovate is approved for this age group.
- Alprolix will be available for children under 18 years of age for prophylaxis until Rebinyn is approved for this age group.
- A process for accessing Eloctate and Alprolix for the above indications is being developed.
- When a new Ig product is started, either as initial treatment or because of a change in current treatment, a minority of patients may experience mild to moderate infusion-related adverse effects. For this reason, it is recommended health-care providers conduct individual risk assessments and monitor patients during the switching process.
- Please remember that adverse reactions associated with a plasma protein product should be reported directly to the manufacturer of the implicated product. Contact information associated with the various plasma protein products distributed by Canadian Blood Services may be found at www.blood.ca in the plasma protein products section. Additional information may be found in the [Guide to Reporting Adverse Transfusion Events](#).

CONTACT US

Day-to-day operations and additional information on products and inventory: Contact your local Canadian Blood Services site or Jennifer Davis, plasma protein products and services team, jennifert.davis@blood.ca.

New products and product support:

Hizentra CARE	1-888-490-4105	
Shire	1-888-999-0287	OnePath 1-844-691-7284
Novo Nordisk	1-800-465-4334	

March 2018

Product category	Product	Size	Target month phase-in	Target month phase-out	Fiscal Year usage (Vials)	
Intravenous immune globulin	Gammagard Liquid	5 g	Available			
		10 g	Limited Quantities			
		2.5 g, 20 g, 30 g	April 2018			
	Panzyga	2.5 g, 5 g,			Out of Stock	
		10 g			June 2018	(612)
		20 g, 30g			September 2018	(20g = 3,540) (30g = 2,734)
	Privigen	2.5 g, 5 g, 20 g	Available			
		10 g			October 2018	(5,333)
		40 g			August 2018	(2,959)
Subcutaneous immune globulin	Cuvitru	1 g, 2 g	Available			
		4 g, 8 g	April 2018			
	Hizentra	1 g vials			Out of Stock	
		2 g vials			March 2018	
		1 g, 2 g pre-filled syringes	Available		November-December 2018	(1g = 8, 218) (2g = 53,744)
		4 g, 10 g			September 2018	(4g = 13,248) (10g = 6,990)
Albumin	Plasbumin (Grifols)	5% 250 mL		December 2018	(25,052)	
Albumin	Albumin (Grifols)	5% 250 mL	August 2018			
Long-acting recombinant factor VIII (Note 1)	Adynovate	250 IU, 500 IU, 1000 IU, 2000 IU	April 2018			
	Eloctate*	250 IU		March 2018	(None)	
		500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU			September–December 2018	(TBD)
Long-acting recombinant factor IX (Note 1)	Rebinyn	500 IU, 1000 IU, 2000 IU	April 2018			
	Alprolix*	500 IU		March 2018	(95,293)	
		1000 IU, 2000 IU, 3000 IU			August–September 2018	(TBD)

*Note 1: Quantities of product to remain available on a named- patient basis

NATIONAL INVENTORY UPDATE as of MARCH 2018

PRODUCT	Warehouse		Ottawa	Regina	Winnipeg	British Columbia	Edmonton	Calgary	Dartmouth	Newfoundland	Brampton (0020)
	Head Office	Brampton	Units on hand	Units on hand	Units on hand	Units on hand	Units on hand	Units on hand	Units on hand	Units on hand	Units on hand
rFIXFc Alprolix 500 IU BIOGEN	-	-	10	-	18	-	-	19	12	20	5
rFIXFc Alprolix 1000 IU BIOGEN	38	103	39	28	4	19	2	20	1	-	66
rFIXFc Alprolix 2000 IU BIOGEN	-	321	79	42	18	40	73	12	6	31	65
rFIXFc Alprolix 3000 IU BIOGEN	54	299	39	24	15	-	37	10	23	10	66
rFVIII Adynovate 250 IU Shire	206	126	20	20	50	60	90	40	20	20	320
rFVIII Adynovate 500 IU Shire	56	46	20	20	60	20	60	20	36	40	130
rFVIII Adynovate 2000 IU Shire	123	137	60	20	20	100	130	40	46	30	300
rFVIIIc BDD Eloctate 250 IU BIOGEN	-	-	-	28	-	33	-	-	-	17	-
rFVIIIc BDD Eloctate 500 IU BIOGEN	32	138	-	24	26	38	27	5	24	55	37
rFVIIIc BDD Eloctate 750 IU BIOGEN	40	38	-	-	8	10	20	-	-	-	80
rFVIIIc BDD Eloctate 1000 IU BIOGEN	121	432	16	16	28	80	56	67	5	53	221
rFVIIIc BDD Eloctate 1500 IU BIOGEN	171	488	2	-	-	87	43	60	32	28	279
rFVIIIc BDD Eloctate 2000 IU BIOGEN	771	710	28	-	40	141	158	20	81	24	197
rFVIIIc BDD Eloctate 3000 IU BIOGEN	323	650	30	-	42	120	56	10	31	118	153
IVIG Gammagard Liquid 10% 2.5g Baxter	38	40	10	-	-	-	30	16	8	10	18
IVIG Gammagard Liquid 10% 5g Baxalta	395	367	115	18	22	17	71	48	3	18	109
IVIG Gammagard Liquid 10% 10g Baxalta	918	386	47	10	6	8	190	46	115	48	127
IVIG Gammagard Liquid 10% 20g Baxalta	1,222	570	118	29	36	42	141	125	23	48	61
IVIG Gammagard Liquid 10% 30g Baxalta	232	292	54	18	36	72	72	4	55	58	69
IVIG Gamunex 10% 2.5g Grifols	286	166	54	27	10	101	27	27	13	9	45
IVIG Gamunex 10% 5g Grifols	1,567	641	117	61	114	199	170	158	80	59	322
IVIG Gamunex 10% 10g Grifols	717	1,379	173	172	240	389	168	264	157	101	336
IVIG Gamunex 10% 20g Grifols	4,828	3,607	523	302	516	895	396	460	292	836	1,786
IVIG IGIVnax 10% 20g CBS/Grifols	-	-	111	209	38	301	96	-	230	302	257
IVIG PANZYGA 10% 50ml/ 5.0g OCTAPHARMA	-	-	-	-	-	-	-	-	-	-	-
IVIG PANZYGA 10% 100ml/10.0g OCTAPHARMA	93	-	17	9	60	60	37	45	36	10	100
IVIG PANZYGA 10% 200ml/20.0g OCTAPHARMA	46	-	24	15	102	144	77	55	79	29	219
IVIG PANZYGA 10% 300ml/30.0g OCTAPHARMA	960	1,407	59	3	32	32	40	25	18	30	134
IVIG Privigen 10% 5g CSL	151	10	32	13	17	81	13	31	51	52	156
IVIG Privigen 10% 10g CSL	103	200	45	27	38	98	28	162	49	60	159
IVIG Privigen 10% 20g CSL	243	497	78	48	68	229	29	278	109	29	278
IVIG Privigen 10% 2.5g CSL	-	-	16	8	-	7	15	-	15	-	41
IVIG Privigen 10% 40g CSL	195	156	48	47	14	55	16	39	17	-	197
SCIG Cuvitru 20% 5ml/1g Baxalta	1,765	2,162	80	30	60	80	100	-	41	20	60
SCIG Cuvitru 20% 10ml/2g Baxalta	6,553	8,093	700	60	430	481	1,383	255	190	180	1,600
SCIG Cuvitru 20% 40ml/8g	9	2,010	60	10	30	48	-	-	30	20	100
SCIG Hizentra 20% 10ml/2g CSL	-	-	-	5	-	-	-	-	-	-	-
SCIG Hizentra 20% 20ml/4g CSL	1,370	1,817	946	83	373	389	565	111	235	83	415
SCIG Hizentra 20% 50ml / 10g CSL	533	1,570	259	52	18	154	2	106	62	4	287
SCIG Hizentra Pre-Filled SYN 10ml/2g CSL	14,381	3,973	186	108	1,072	712	2,298	88	226	222	1,166
SCIG Hizentra Pre-Filled SYN 5ml/1g CSL	578	450	141	44	564	274	89	280	112	5	170
Albumin Alburex 25% 100mL CSL	-	60	419	147	134	226	519	212	722	-	2,011
Albumin Alburex 25% 50ml CSL	163	43	14	50	31	48	39	16	50	109	101
Albumin 25% 100mL CBS/Grifols	18,174	7,008	1,232	329	479	856	613	309	433	642	2,151
Albumin Plasbumin 25% 100mL Grifols	-	-	-	-	-	-	-	-	-	-	4
Albumin Alburex 5% 250mL CSL	220	6	-	51	53	71	22	-	450	-	49
Albumin Alburex 5% 500mL CSL	246	2,692	511	286	324	414	168	398	301	50	1,648
Albumin Plasbumin 5% 50mL Grifols	146	267	35	6	6	52	87	34	21	19	40
Albumin 5% 250mL CBS/Grifols	7,725	1,949	-	-	201	651	220	30	-	-	3
Albumin Plasbumin 5% 250mL Grifols	6,028	5,617	300	41	451	2	438	63	261	226	670

INTRAVENEOUS IMMUNE GLOBULINS

BRAND NAME	IGIVnex and GAMUNEX [®]	Gammagard S/D		Gammagard Liquid	Privigen [®]	Panzyga [®]
WEBLINK	www.grifols.com	http://www.baxalta.ca/products_en.html			www.cslbehring.ca	www.octapharma.ca
SIZES	5 g, 10 g, 20 g Only 20 g for IGIVnex	5 g		2.5 g, 5 g, 10 g, 20 g, 30 g	2.5 g, 5 g, 10 g, 20 g, 40 g	10 g, 20 g, 30 g
INDICATIONS	PID, SID, ITP, CIDP, GBS	PID, CLL, ITP		PID, SID, ITP, MMN	PID, SID, ITP, CIDP	PID, SID, ITP
CONCENTRATION	10%	5% or 10% upon reconstitution		10%	10%	10%
IgA CONTENT	Not more than 0.084 mg/mL	≤ 2.2 µg/mL in 5% solution		≤ 0.14 mg/mL	No more than 25 mcg/mL	≤ 0.3 mg/mL
SUGAR CONTENT	Not indicated in product monograph	20 mg/mL dextrose in 5%		None	Not indicated in product monograph	Not indicated in product monograph
STORAGE TEMPERATURE	+2°C to +8°C	Not to exceed +25°C		+2 to +8°C	+2°C to +25°C	+2°C to +8 °C
INITIAL Recommended INFUSION RATE	0.01 to 0.02 mL/kg/min (1 to 2 mg/kg/min) for the first 30 mins	5% and 10% Solution 0.5 mL/kg of body weight/hr		0.5 mL/kg of BW/hr for 30 mins BW=body weight	0.5 mg/kg/min (0.3 mL/kg/hr)	1 mg/kg/min for the first 30 mins
MAXIMUM Recommended INFUSION RATE	0.14 mL/kg/min (14 mg/kg/min)	<u>5% Solution</u> 4 mL/kg/hr	<u>10% Solution</u> 8 mL/kg/hr	8 mL/kg of BW/hr <u>For MMN</u> 5.4 mL/kg of body weight/hr	12 mg/kg/min (7.2 mL/kg/hr)	8 mg/kg/min (in new patients) <u>For PID & SID</u> 12 or 14 mg/kg/min (in experienced patients)

2018-03-20

This Table is a summary and will not tell you everything about IG products. Detailed information can be found in the product monograph or product insert.

CONTENT is subject to change.

SUBCUTANEOUS IMMUNE GLOBULINS

BRAND NAME	IGIVnex and GAMUNEX [®]	Hizentra [™]	Cuvitru [™]	*Gammanorm [®] Special Access Programme
WEBLINK	www.grifols.com	www.cslbehring.ca	www.shirecanada.com	www.octapharma.ca
SIZES	5 g, 10 g, 20 g, Only 20g for IGIVnex	1 g(PFS), 2 g(PFS), 4 g, 10 g	1 g, 2 g, 4 g, 8 g	1.65 g
INDICATIONS	Primary Immune Deficiency (PID) Secondary Immune Deficiency (SID)			Primary Immune Deficiency (PID)
CONCENTRATION	10%	20%	20%	16.5%
IgA CONTENT	Not more than 0.084 mg/mL	No more than 50 mg/L	Average <80 mcg/mL No more than 280 mcg/mL	Not indicated in PI
SUGAR CONTENT	Not indicated in product monograph	None	Not indicated in product monograph	None
STORAGE TEMPERATURE	+2°C to +8°C	+2°C to +25°C	+2°C to +8°C	+2°C to +8°C
RECOMMENDED INFUSION RATE	20 mL/hr per infusion site	15 mL/hr per site	≤60 mL/hr/site up to 4 sites	As per physician's prescription

* Not licensed in Canada but is available via Special Access Programme.

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