DRUG NAME: Daratumumab

SYNONYM(S): HuMax-CD38[1]

COMMON TRADE NAME(S): DARZALEX®, DARZALEX® SC

CLASSIFICATION: molecular targeted therapy

Special pediatric considerations are noted when applicable, otherwise adult provisions apply.

MECHANISM OF ACTION:

Daratumumab is a human IgG1 kappa monoclonal antibody that targets the transmembrane glycoprotein CD38. It potently inhibits the growth of CD38-expressing tumour cells and may induce tumour cell lysis by utilizing multiple effector functions in malignancies expressing CD38. Daratumumab has direct and indirect antitumour activity including complement-dependent cytotoxicity, antibody-dependent cell-mediated cytotoxicity, antibody-dependent cellular phagocytosis, induction of apoptosis, and immunomodulatory functions that deplete immune suppressor cells, leading to T-cell expansion and activation.[2,3]

PHARMACOKINETICS:

Absorption	increases in Cmax and AUC are more than dose-proportional after repeat dosing[4]; peak concentrations after subcutaneous injection occur 70-72 h[5]	
Distribution	target-mediated disposition, primarily confined to the vascular system with limited extravascular distribution[4]	
	cross blood brain barrier?	no information found
	volume of distribution[5,6]	IV: 4.4-4.7 L SC: 3.8-5.3 L
	plasma protein binding	no information found
Metabolism	likely catabolically metabolized via degradation into small peptides and amino acids;	
	active metabolite(s)	no information found
	inactive metabolite(s)	no information found
Excretion	clearance decreases with increasing dose and repeat dosing[1,2]; cleared by parallel linear and nonlinear saturable target mediated clearances[5]	
	urine	no information found
	feces	no information found
	terminal half life[2,5]	IV: 9 days (single dose); 18 days (repeat dosing) SC: 20 days
	clearance[4]	0.42 mL/h/kg (single dose); 0.3 mL/h/kg (repeat dosing)

Adapted from standard reference[2] unless specified otherwise.

USES:

Primary uses:

*Amyloidosis

*Multiple myeloma

Other uses:

*Health Canada approved indication

Developed: 1 January 2018
Revised: 1 January 2024

SPECIAL PRECAUTIONS:

Contraindications:
- history of hypersensitivity reaction to daratumumab or Chinese Hamster Ovary cell proteins[7]
- (for subcutaneous formulation only) history of hypersensitivity reaction to hyaluronidase[7]

Caution:
- daratumumab formulations for intravenous infusion and subcutaneous administration are ***NOT interchangeable;*** formulations differ in concentration and dosing[5]
- ***infusion reactions*** are sometimes reported; pre-medicate with corticosteroids, antihistamines, and antipyretics and administer post-infusion corticosteroids[2]
- patients with ***chronic obstructive pulmonary disease*** may require additional short and long acting bronchodilators plus inhaled corticosteroids post-infusion[2]
- ***herpes zoster reactivation*** may occur; initiate antiviral prophylaxis within one week of starting treatment and continue for three months following treatment completion[2,6]
- ***hepatitis B reactivation*** has been reported with daratumumab[8,9]; for recommended HBV screening and prophylaxis, see BC Cancer Protocol SCHBV ***Hepatitis B Virus Reactivation Prophylaxis***.[10]
- daratumumab interferes with ***cross-matching*** and ***red blood cell antibody screening***; type and screen patients prior to initiating daratumumab treatment if possible[6]

Special populations: Neonates or infants exposed to daratumumab *in utero* should not receive live vaccines until a hematological evaluation has been completed.[2]

Carcinogenicity: no information found

Mutagenicity: no information found

Fertility: no information found

Pregnancy: Human and animal studies are not available, however IgG1 monoclonal antibodies are known to cross the placenta. Based on its mechanism of action, daratumumab may cause fetal myeloid or lymphoid cell depletion and decreased bone density. Women of childbearing potential should use effective contraception during treatment and for at least three months after discontinuation.[2]

Breastfeeding is not recommended due to the potential secretion into breast milk. Human IgG is known to be secreted in human breast milk.[2]

SIDE EFFECTS:

The table includes adverse events that presented during drug treatment but may not necessarily have a causal relationship with the drug. Because clinical trials are conducted under very specific conditions, the adverse event rates observed may not reflect the rates observed in clinical practice. Adverse events are generally included if they were reported in more than 1% of patients in the product monograph or pivotal trials, and/or determined to be clinically important.[11,12]

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in ***bold, italics***	
blood and lymphatic system/ febrile neutropenia (see paragraph following **Side Effects** table)	***anemia*** (27-45%, severe 17-19%)[2,13]
	leukopenia (10-57%, severe 5-19%)
	lymphopenia (6-72%, severe 6-40%)[2,13]
	neutropenia (22-60%, severe 12-20%)[2,13]

Developed: 1 January 2018
Revised: 1 January 2024

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in ***bold, italics***	
	thrombocytopenia (20-48%, severe 14-18%)[2,13]
cardiac	palpitations (3%)
eye	blurred vision (6%)
gastrointestinal	*emetogenic potential:* low[14]
	abdominal pain (6%, severe 1%)
	constipation (15%)
	diarrhea (16%, severe <1%)
	dyspepsia (3%)
	nausea (27%)
	stomatitis (3%)
	toothache (3%)
	vomiting (14%)
general disorders and administration site conditions	*extravasation hazard:* none[15]
	asthenia (8%, severe <1%)
	chills (10%)
	fatigue (39%, severe 2%)
	flu-like symptoms (5%, severe <1%)
	injection site reactions (SC)[5,16] (7-8%, severe 0%); erythema, induration, pruritus
	non-cardiac chest pain, discomfort (3-12%, severe 1%)
	pain (5%, severe <1%)
	peripheral edema (7%, severe <1%)
	physical health deterioration (3%, severe <1%))
	pyrexia (21%, severe <1%)
hepatobiliary	hepatic impairment (4%, severe <1%)
immune system (see paragraph following **Side Effects** table)	***administration-related systemic reactions***[16] **(*SC*):** initial injection (8-13%, severe <2%); subsequent injections (<1%, severe <1%)
	cytokine release syndrome (<2%)
	infusion-related reactions (IV): initial infusion (35-48%, severe 5-7%)[2,16], subsequent infusions (2-4%, severe <1%)
infections and infestations (see paragraph following **Side Effects** table)	hepatitis B reactivation[8] (<1%)
	herpes zoster (3%, severe 1%)
	influenza (3%)
	pneumonia (11%, severe 6%)
	upper respiratory tract infection (5-39%, severe 2%)
	urinary tract infection (6%)

Developed: 1 January 2018
Revised: 1 January 2024

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in ***bold, italics***	
investigations	AST increase (20%, severe 1%)
	creatinine increase (21%, severe 2%)
	weight gain (3%)
	weight loss (5%, severe <1%)
metabolism and nutrition	anorexia (14%, severe <1%)
	hypercalcemia (12-32%, severe 3-7%)
	hyperglycemia (8%, severe 3%)
	hyperkalemia (3%, severe <1%)
	hyperuricemia (3%, severe <1%)
	hypoalbuminemia (3-41%, severe 3%)
	hypocalcemia (32%)
	hypokalemia (8%, severe <1%)
	hypomagnesemia (6%)
	hyponatremia (5-29%, severe 4%)
musculoskeletal and connective tissue	arthralgia (17%)
	back pain (23%, severe 2%)
	bone pain (10%, severe <1%)
	muscle spasms (6%)
	myalgia (4%)
	pain in extremity (15%, severe <1%)
nervous system	dizziness (8%)
	headache (12%, severe 1%)
	hypoesthesia (5%)
	peripheral sensory neuropathy (4%)
	somnolence (3%, severe <1%)
	tremor (3%)
psychiatric	anxiety (6%)
	confusion (5%, severe 1%)
	insomnia (5%)
renal and urinary	dysuria (3%)
	renal impairment (7%, severe 1%)
respiratory, thoracic and mediastinal	allergic rhinitis (7%)
	bronchospasm (3%, severe 1%)
	cough (21%), productive cough (5%)

Developed: 1 January 2018
Revised: 1 January 2024

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in ***bold, italics***	
	dyspnea (5-15%, severe <1%)
	epistaxis (6%)
	nasal/sinus congestion (5-17%)
	oropharyngeal pain (10%)
	pleural effusion (3%)
	sneezing (3%)
	throat irritation (6%)
	wheezing (5%)
skin and subcutaneous tissue	dry skin (3%)
	hyperhidrosis (3%)
	rash (3%)
	pruritus (3%)
vascular	hematoma (3%)
	hypertension (10%, severe 5%)
	hypotension (5%, severe <1%)

Adapted from standard reference[2] unless specified otherwise.

Infusion-related reactions are reported in up to 50% of patients during the first infusion and in 2-4% of patients during subsequent infusions. Reactions generally occur during administration of the infusion or within four hours of its completion. Respiratory symptoms (e.g., cough, wheeze, larynx and throat irritation, nasal congestion), chills, nausea, and vomiting may occur. Severe reactions have also been reported, including bronchospasm, laryngeal and pulmonary edema, hypertension, hypoxia, and dyspnea. To minimize the risk of reaction, premedication with antihistamines, antipyretics, and corticosteroids is recommended. To prevent delayed reactions, oral corticosteroids may also be administered for two days following the infusion, starting one day post-infusion. When dexamethasone is prescribed as part of combination chemotherapy, additional corticosteroid therapy may not be necessary post-infusion. Follow incremental infusion rate increases closely and monitor patients during the entire infusion. Interrupt treatment for reactions of any grade/severity and promptly manage symptoms. Following resolution of a grade 3 (or less) reaction, the infusion may be resumed at a reduced rate of no more than half of the previous rate. Permanently discontinue daratumumab upon the third occurrence of a grade 3 reaction or following a grade 4 (life-threatening) reaction.[2,6,13] For management of infusion-related reactions, see BC Cancer Protocol SCDRUGRX ***Management of Infusion-Related Reactions to Systemic Therapy Agents***.

Like infusion-related reactions following IV administration, ***administration-related systemic reactions*** have been reported following ***subcutaneous*** injection of daratumumab. Signs and symptoms are consistent with those reported for the intravenous formulation. Approximately 10% of patients report these reactions with subcutaneous daratumumab, usually following the first injection. Reactions with subsequent subcutaneous injections are reported in less than 1% of patients. Most reactions are grade 1 or 2, but severe reactions, including anaphylaxis, have been reported (rare). The majority of reactions occur on the day of treatment with a median time to onset of 3.7 hours (range 0.15-83 hours). Delayed reactions are reported in less than 1% of patients. Premedication with antihistamines, antipyretics, and corticosteroids and post-injection corticosteroids are recommended to reduce the risk of administration-related reactions with subcutaneous daratumumab. Manage reactions as clinically appropriate and permanently discontinue subcutaneous daratumumab for grade 4 reactions.[5]

Developed: 1 January 2018
Revised: 1 January 2024

Patients with a history of ***chronic obstructive pulmonary disease*** may have an increased risk of respiratory complications associated with infusion-related reactions. Additional short or long acting bronchodilators and inhaled corticosteroids may be required post-infusion. If no major infusion-related reactions occur during the first four infusions, consider discontinuing the additional inhaled medications.[2]

Daratumumab may increase the ***hematologic toxicity*** (i.e., neutropenia, thrombocytopenia) of other chemotherapeutic agents when given in combination. Daratumumab dose reduction is not required; however, treatment interruption may be required to allow for neutrophil and/or platelet recovery. Supportive care with growth factors and/or platelet transfusions may also be necessary.[2]

Severe, life-threatening, and fatal ***infections*** are reported with a higher incidence when daratumumab is given in combination with other chemotherapeutic agents. Patients with neutropenia should be closely monitored for signs of infection and promptly treated.[2]

INTERACTIONS:

AGENT	EFFECT	MECHANISM	MANAGEMENT
Coombs test (indirect antiglobulin test)[2]	false positive Coombs test may persist for up to six months post treatment; detection of antibodies to minor serum antigens may be masked	daratumumab binds to CD38 on red blood cells	• type and screen patients prior to starting daratumumab if possible[6] • if emergency transfusion is required, non-cross-matched ABO/RhD-compatible RBCs can be given[17]
Serum protein electrophoresis (SPE) and immunofixation (IFE) assays[2]	false positive SPE and IFE assay results in patients with IgG kappa M-protein	daratumumab is detected on SPE and IFE assays used for monitoring endogenous M-protein	• additional tests may be required to evaluate response

SUPPLY AND STORAGE:

Injection:
Janssen Inc. supplies daratumumab for intravenous use (DARZALEX®) as 100 mg and 400 mg single-use (preservative free) vials in a concentration of 20 mg/mL. Refrigerate. Do not shake. Protect from light.[18]

Janssen Inc. supplies daratumumab for subcutaneous use (DARZALEX® SC) as 1800 mg ready-to-use, single-dose (preservative free) vials in a concentration of 120 mg/mL. Refrigerate. Do not shake. Protect from light.[19]

Additional information:
- human ***hyaluronidase*** (rHuPH20) is an enzyme used to increase the dispersion and absorption of other drugs administered subcutaneously (such as daratumumab subcutaneous), allowing for a larger injection volume to be administered with limited swelling or pain; hyaluronidase has a half-life in skin of less than 30 minutes and subcutaneous tissue returns to normal within 24-48 h after injection[19]
- ***unpunctured vials*** of daratumumab for ***subcutaneous*** use may be stored at ambient light and temperature for up to 24 hours prior to injection if kept out of direct sunlight[19]

For basic information on the current brand used at BC Cancer, see Chemotherapy Preparation and Stability Chart in Appendix.

Developed: 1 January 2018
Revised: 1 January 2024

SOLUTION PREPARATION AND COMPATIBILITY:

For basic information on the current brand used at BC Cancer, see Chemotherapy Preparation and Stability Chart in Appendix.

Additional information:

- *Intravenous* formulation:
  - diluted solution may develop small, translucent to white proteinaceous particles; do not use if visible opaque particles are observed[18]
  - administer with a 0.22 or 0.2 micron low protein binding in-line filter[18]
  - compatibility data supports compounding to a final concentration of 0.4 to 4.5 mg/mL[20]
- *Subcutaneous* formulation:
  - equilibrate vials to ambient temperature prior to use[19]

Compatibility: consult detailed reference

PARENTERAL ADMINISTRATION:

BC Cancer administration guideline noted in ***bold***, ***italics***

<table>
<tr><td>Subcutaneous[19,21-25]
(use subcutaneous formulation only†)</td><td colspan="5">over 3-5 min into the abdomen; pause or slow delivery if patient experiences pain on injection
if pain is not alleviated, a second injection site may be used to administer the remainder of the dose</td></tr>
<tr><td>Intramuscular</td><td colspan="5">no information found</td></tr>
<tr><td>Direct intravenous</td><td colspan="5">do NOT use[13]</td></tr>
<tr><td rowspan="6">Intermittent infusion[18,21-25]
(use IV formulation only†)</td><td colspan="5">over 3.25-15 h[18,21-25]; rapid infusion (over 90 min) has been used[26-29]
Refer to protocol by which patient is being treated.</td></tr>
<tr><td colspan="5">In the absence of other guidelines, the following incremental infusion rate may be used[18,21]</td></tr>
<tr><td></td><td>Dilution volume</td><td>Initial rate (first hour)</td><td>Rate increment[a]</td><td>Maximum rate</td></tr>
<tr><td>Cycle 1, day 1*</td><td>1000 mL</td><td>50 mL/h</td><td>50 mL/h every hour</td><td>200 mL/h</td></tr>
<tr><td>alternate regimen*: Cycle 1, days 1,2</td><td>500 mL</td><td>50 mL/h</td><td>50 mL/h every hour</td><td>200 mL/h</td></tr>
<tr><td>Cycle 1, day 8[b]</td><td>500 mL</td><td>50 mL/h</td><td>50 mL/h every hour</td><td>200 mL/h</td></tr>
<tr><td>subsequent nfusions[c]</td><td>500 mL</td><td>100 mL/h</td><td>50 mL/h every hour</td><td>200 mL/h</td></tr>
<tr><td>Continuous infusion</td><td colspan="5">no information found</td></tr>
<tr><td>Intraperitoneal</td><td colspan="5">no information found</td></tr>
<tr><td>Intrapleural</td><td colspan="5">no information found</td></tr>
<tr><td>Intrathecal</td><td colspan="5">no information found</td></tr>
<tr><td>Intra-arterial</td><td colspan="5">no information found</td></tr>
<tr><td>Intravesical</td><td colspan="5">no information found</td></tr>
</table>

[a]escalate only in the absence of infusion reactions
[b]escalate only if there were no infusion-related reactions during the first 3 hours of the **first** infusion
[c]escalate only if there were no infusion-related reactions during a final infusion rate of ≥100 mL/h during the **first two** infusions
*Alternate regimen: the first dose of daratumumab (cycle 1, day 1) is split into two equal doses and administered over two consecutive days (becoming cycle 1, days 1 and 2).
† daratumumab for subcutaneous use (DARZALEX® SC) is intended **for subcutaneous use** only and is not interchangeable with daratumumab formulations that are intended for other routes of administration.

Developed: 1 January 2018
Revised: 1 January 2024

DOSAGE GUIDELINES:

Refer to protocol by which patient is being treated. Numerous dosing schedules exist and depend on disease, response, and concomitant therapy. Guidelines for dosing also include consideration of absolute neutrophil count (ANC). Dosage may be reduced, delayed or discontinued in patients with bone marrow depression due to cytotoxic/radiation therapy or with other toxicities.

***Adults*:**

BC Cancer usual dose noted in ***bold, italics***

	Cycle Length:	
Intravenous: *(use IV formulation only†)*	***4 weeks***[18,21-24]:	**Cycles 1, 2:** ***16 mg/kg IV for one dose* on days 1, 8, 15, and 22*** (total dose per cycle 64 mg/kg) *Alternate regimen for Cycle 1 day 1 (split dosing): ***8 mg/kg IV for one dose on days 1 and 2*** (total dose per cycle 64 mg/kg) **Cycles 3-6:** ***16 mg/kg IV for one dose on days 1 and 15*** (total dose per cycle 32 mg/kg) **Cycle 7 onward:** ***16 mg/kg IV for one dose on day 1*** (total dose per cycle 16 mg/kg)
	4 weeks[18,25]:	**Cycles 1, 2:** ***16 mg/kg IV for one dose* on days 1, 8, 15, and 22*** (total dose per cycle 64 mg/kg) *Alternate regimen for Cycle 1 day 1 (split dosing): ***8 mg/kg IV for one dose on days 1 and 2*** (total dose per cycle 64 mg/kg) **Cycles 3-4:** ***16 mg/kg IV for one dose on days 1 and 15*** (total dose per cycle 32 mg/kg) **Cycle 5 onward:** ***16 mg/kg IV for one dose on day 1*** (total dose per cycle 16 mg/kg)
	3 weeks[18]:	Cycles 1-3 (q3weekly): 16 mg/kg IV for one dose on days 1, 8, and 15 (total dose per cycle 48 mg/kg) Cycle 4-8 (q3weekly): 16 mg/kg IV for one dose on day 1 (total dose per cycle 16 mg/kg)

Developed: 1 January 2018
Revised: 1 January 2024

BC Cancer usual dose noted in ***bold, italics***

	Cycle Length:	Cycle 9 onward (change to q4weekly): 16 mg/kg IV for one dose on day 1 (total dose per cycle 16 mg/kg)
	6 weeks[18]:	Cycle 1 (q6weekly): 16 mg/kg IV for one dose on days 1, 8, 15, 22, 29, and 36 (total dose per cycle 96 mg/kg) Cycles 2-9 (q6weekly): 16 mg/kg IV for one dose on days 1 and 22 (total dose per cycle 32 mg/kg) Cycle 10 onward (change to q4 weekly): 16 mg/kg IV for one dose on day 1 (total dose per cycle 16 mg/kg)
Subcutaneous: *(use subcutaneous formulation only†)*	***4 weeks***[19,21-24]:	**Cycles 1, 2**: ***1800 mg SC for one dose on days 1, 8, 15, and 22*** (total dose per cycle 7200 mg) **Cycles 3-6**: ***1800 mg SC for one dose on days 1 and 15*** (total dose per cycle 3600 mg) ***Cycle 7 onward***: ***1800 mg SC for one dose on day 1*** (total dose per cycle 1800 mg)
	4 weeks[19,25]:	**Cycles 1, 2:** ***1800 mg SC for one dose* on days 1, 8, 15, and 22*** (total dose per cycle 7200 mg) **Cycles 3-4:** ***1800 mg SC for one dose on days 1 and 15*** (total dose per cycle 3600 mg) **Cycle 5 onward:** ***1800 mg SC for one dose on day 1*** (total dose per cycle 1800 mg)
	3 weeks[19]:	Cycles 1-3 (q3weekly): 1800 mg SC for one dose on days 1, 8, and 15 (total dose per cycle 5400 mg) Cycles 4-8 (q3weekly): 1800 mg SC for one dose on day 1 (total dose per cycle 1800 mg)

Developed: 1 January 2018
Revised: 1 January 2024

BC Cancer usual dose noted in ***bold, italics***

	Cycle Length:	
		Cycle 9 onward (change to q4weekly): 1800 mg SC for one dose on day 1 (total dose per cycle 1800 mg)
	6 weeks[19]:	Cycle 1 (q6weekly): 1800 mg SC for one dose on days 1, 8, 15, 22, 29, and 36 (total dose per cycle 10,800 mg)
		Cycles 2-9 (q6weekly): 1800 mg SC for one dose on days 1 and 22 (total dose per cycle 3600 mg)
		Cycle 10 onward (change to q4weekly): 1800 mg SC for one dose on day 1 (total dose per cycle 1800 mg)
Concurrent radiation:	no information found	
Dosage in myelosuppression[2]*:*	dose adjustment is not recommended, however to allow for recovery, dose may be delayed; refer to protocol by which patient is being treated	
Dosage in renal failure[2]*:*	no starting dose adjustment required	
Dosage in hepatic failure[2]*:*	mild impairment: no adjustment required moderate/severe impairment: no information found	
Dosage in dialysis:	no information found	

† daratumumab for subcutaneous use (DARZALEX® SC) is intended for subcutaneous use only and is not interchangeable with daratumumab formulations that are intended for other routes of administration.

Children: no information found

REFERENCES:

1. Lokhorst HM, Plesner T, Laubach JP, et al. Targeting CD38 with Daratumumab Monotherapy in Multiple Myeloma. N.Engl.J.Med. 2015;373(13):1207-1219
2. Janssen Inc. DARZALEX® product monograph. Toronto, Ontario; 13 April 2017
3. Palumbo A, Chanan-Khan A, Weisel K, et al. Daratumumab, Bortezomib, and Dexamethasone for Multiple Myeloma. N Engl J Med 2016;375(8):754-766
4. Clemens PL, Yan X, Lokhorst HM, et al. Pharmakokinetics of Daratumumab following intravenous infusion in relapsed or refractory multiple myeloma after prior proteasome inhibitor and immunomodulatory drug treatment. Clin Pharmacokinet 2017;56:915-924
5. Janssen Inc. DARZALEX® SC product monograph. Toronto, Ontario; 29 July 2020
6. Janssen Biotech Inc. DARZALEX® full prescribing information. Horsham, PA, USA; Jun 2017
7. Hoffmann-La Roche Ltd. RITUXAN® SC product monograph. Mississauga, Ontario; September 9 2016

Developed: 1 January 2018
Revised: 1 January 2024

8. Janssen Inc. Important Safety Information on DARZALEX® (daratumumab) and Hepatitis B Virus Reactivation. Ottawa, Ontario; 25 March 2019
9. Health Canada. MedEffect® e-Notice - DARZALEX® (daratumumab) and Hepatitis B Virus Reactivation. 2019. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html. Accessed 25 March, 2019
10. BC Cancer Supportive Care Tumour Group. (SCHBV) BC Cancer Protocol Summary for Hepatitis B Virus Reactivation Prophylaxis. Vancouver, British Columbia: BC Cancer; September 1 2023
11. Linda Hamata RPh BC Cancer Agency Lymphoma & Myeloma Tumour Group. Personal communication. 3 December2017
12. Kevin Song MD. BC Cancer Agency Lymphoma & Myeloma Tumour Group. Personal communication. 1 December2017
13. Lexicomp Online® (database on the Internet). Daratumumab. Lexi-Comp Inc., 2017. Available at: http://online.lexi.com. Accessed 11 October, 2017
14. BC Cancer Agency. (SCNAUSEA) Guidelines for Prevention and Treatment of Chemotherapy-induced Nausea and Vomiting in Adults. Vancouver, British Columbia: BC Cancer Agency; 1 Mar 2012
15. BC Cancer Agency Provincial Systemic Therapy Program. Provincial Systemic Therapy Program Policy III-20: Prevention and Management of Extravasation of Chemotherapy. Vancouver, British Columbia: BC Cancer Agency; 1 November 2014
16. Janssen Inc. DARZALEX® SC product monograph. Toronto, Ontario; June 22, 2022
17. AHFS Drug Information® (database on the Internet). Daratumumab. Lexi-Comp Inc., 2016. Available at: http://online.lexi.com. Accessed 11 October, 2017
18. Janssen Inc. DARZALEX® product monograph. Toronto, Ontario; December 8 2021
19. Janssen Inc. DARZALEX® SC product monograph. Toronto, Ontario; January 21, 2022
20. Laura-Lee Elms BScPharm. Senior Medical Information Associate and Janssen Inc. Personal communication: DARZALEX® (daratumumab). 4 September2018
21. Chari A, Usmani SZ, Krishnan A, et al. Daratumumab (DARA) in Combination with Carfilzomib, Lenalidomide, and Dexamethasone (KRd) in Patients with Newly Diagnoses Multiple Myeloma (MMY1001): Updated Results From an Open-label, Phase Ib Study. Poster Presentation American Society of Hematology (ASH) Annual Meeting and Exposition.December 9-12, 2017
22. BC Cancer Myeloma Tumour Group. (UMYDARCBDF) BC Cancer Protocol Summary for the Treatment of Previously Untreated Multiple Myeloma and Not Eligible for Stem Cell Transplant using Daratumumab, Cyclophosphamide, Bortezomib and Dexamethasone. Vancouver, British Columbia: BC Cancer; September 1 2022
23. BC Cancer Myeloma Tumour Group. (UMYDARLD) BC Cancer Protocol Summary for the Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Lenalidomide and Dexamethasone. Vancouver, British Columbia: BC Cancer; September 1 2022
24. BC Cancer Myeloma Tumour Group. (UMYDARLDF) BC Cancer Protocol Summary for the Treatment of Previously Untreated Multiple Myeloma and Not Eligible for Stem Cell Transplant using Daratumumab, Lenalidomide and Dexamethasone. Vancouver, British Columbia: BC Cancer; September 1 2022
25. BC Cancer Myeloma Tumour Group. (UMYDARBD) BC Cancer Protocol Summary for the Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone With or Without Cyclophosphamide. Vancouver, British Columbia: BC Cancer; September 1 2022
26. Barr H, Dempsey J, Waller A, et al. Ninety-minute daratumumab infusion is safe in multiple myeloma. Leukemia 2018;32(11):2495-2518
27. Stakiw J, Kukreti V, LeBlanc R, et al. Initial results of MCRN 009: phase 2 study of an accelerated infusion rate of daratumumab in patients with relapsed/refractory multiple myeloma (MM). 17th International Myeloma Workshop (Abstract Book) 2019:Abstract SP-102
28. Gozzetti A, Bacchiarri F, Di Martino F, et al. Long term safety and efficacy of daratumumab rapid intravenous infusion (90 minutes) after the third dose in multiple myeloma patients. 17th International Myeloma Workshop (Abstract Book) 2019:Abstract FP-161
29. Antonioli E, Attardi E, Staderini M, et al. Safety of rapid daratumumab infusion in relapsed and refractory multiple myeloma. 17th International Myeloma Workshop (Abstract Book) 2019:Abstract FP-150

Developed: 1 January 2018
Revised: 1 January 2024