

DRUG NAME: Balstilimab

SYNONYM(S): AGEN2034¹

COMMON TRADE NAME(S):

CLASSIFICATION: immunotherapy

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

MECHANISM OF ACTION:

Balstilimab is a recombinant human IgG4 monoclonal antibody that inhibits programmed cell death 1 (PD-1) as an immune checkpoint inhibitor. The PD-1 pathway is an immune system checkpoint that may be exploited by tumour cells to escape active T-cell surveillance. By blocking the binding of the PD-1 receptor to the PD-1 and PD-2 ligands, balstilimab reactivates tumour-specific cytotoxic T-lymphocytes in the tumour microenvironment and restimulates anti-tumour immunity.¹

USES:

Primary uses:

Colorectal cancer¹

Other uses:

Cervical cancer ¹

Melanoma ¹

*Health Canada approved indication

SPECIAL PRECAUTIONS:

Caution:

- avoid systemic **corticosteroids** or **immunosuppressants** prior to starting balstilimab due to potential interference with the efficacy of balstilimab; corticosteroids or immunosuppressants may be used during treatment for the management of immune-mediated adverse reactions²
- the safety and efficacy of **vaccination** in patients receiving immunotherapy is currently being investigated³⁻⁶

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. **Side effect data reported from combination therapy (e.g., with botensilimab) are indicated with an asterisk (*)**.

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in bold, italics	
blood and lymphatic system/ febrile neutropenia	anemia (11%)
	lymphopenia (3%)
eye	uveitis (<1%)
endocrine	adrenal insufficiency (2%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in <i>bold, italics</i>	
	hyperthyroidism (6%)
	hypopituitarism (<1%)
	hypothyroidism (4%)
gastrointestinal	<i>emetogenic potential</i> : minimal (rare) ⁷
	abdominal pain (3%)
	constipation (3%)
	dry mouth (1%)
	<i>colitis</i> (2%)
	gastritis (<1%)
	<i>diarrhea</i> (13%)
	nausea (11%)
	stomatitis (2%)
	vomiting (4%)
general disorders and administration site conditions	<i>extravasation hazard</i> : none ⁸
	asthenia (13%)
	chills (1%)
	edema, peripheral (2%)
	fatigue (15%)
	<i>infusion-related reaction</i> (1%); see paragraph following Side Effects table
	pyrexia (3%)
immune system (see paragraph following Side Effects table)	<i>adrenal insufficiency</i> (<1%)*
	<i>arthritis</i> (<1%)
	<i>enterocolitis</i> (2%)
	<i>dermatitis</i> (<1%)*
	<i>hepatitis</i> (<1%)*
	<i>hypophysitis</i> (<1%)
	<i>hypothyroidism</i> (4%)
	<i>myocarditis</i> (<1%)*
	<i>myositis</i> (<1%)*
	<i>nephritis</i> (<1%)
	<i>pancreatitis</i> (<1%)
	<i>pneumonitis</i> (<1%)
	<i>thyroiditis</i> (<1%)
investigations	alkaline phosphatase increase (3%)

ORGAN SITE	SIDE EFFECT
Clinically important side effects are in <i>bold, italics</i>	
	<i>ALT increase</i> (3%)
	<i>AST increase</i> (4%)
	blood bilirubin increase (2%)
	creatinine increase (3%)
	weight loss (3%)
metabolism and nutrition	appetite decrease (6%)
	diabetes mellitus, type I (<1%)*; diabetic ketoacidosis reported
	hypokalemia (3%)
	hypomagnesemia (3%)
musculoskeletal and connective tissue	arthralgia (5%)
	muscle spasm (2%)
	myalgia (4%)
psychiatric	insomnia (3%)
nervous system	dizziness (1%)
	dysgeusia (<1%)
	headache (4%)
	peripheral neuropathy (<1%)
renal and urinary	acute kidney injury (<1%)
respiratory, thoracic and mediastinal	cough (3%)
	dyspnea (3%)
	pneumonitis (2%)
skin and subcutaneous tissue	dry skin (1%)
	pruritus (8%)
	rash (7%)
vascular	flushing (1%)

Adapted from standard reference¹ unless specified otherwise.

Immune-mediated adverse reactions are a spectrum of side effects caused by general immunologic enhancement that can occur at any time during balstilimab treatment or months after discontinuation. The etiology of reported endocrinopathy, diarrhea/colitis, dermatitis, hepatitis, pneumonitis, etc. should be considered immune-mediated until another etiology is confirmed. Early identification and timely intervention are important as symptoms can be severe or fatal if not recognized and treated quickly. Advise patients to promptly report symptoms and to avoid self-treatment without medical advice. Management of symptoms is based on the severity of the reaction and may require treatment interruption, corticosteroids, systemic immunosuppressants, and/or supportive care. Dose reduction is not recommended. Referral to appropriate medical specialty may be required to manage immune-mediated complications related to treatment.^{1,2} For further information on management of immune-mediated adverse reactions, see BC Cancer Protocol SCIMMUNE [Management of Immune-Mediated Adverse Reactions to Checkpoint Inhibitors Immunotherapy](#).

Severe ***infusion-related reactions*** have been rarely reported.¹ Patients with mild or moderate infusion reactions may receive balstilimab with close monitoring and premedication for subsequent infusions.² For management of infusion-related reactions, see BC Cancer Protocol SCDRUGRX [Management of Infusion-Related Reactions to Systemic Therapy Agents](#).

INTERACTIONS: no information found

SUPPLY AND STORAGE:

Injection: Agenus Inc. supplies balstilimab as 50 mg single use (preservative free) ready-to-use vials in a concentration of 50 mg/mL. Refrigerate. Protect from light.¹

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

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:

- to prevent extraction of plasticizer DEHP from container, prepare solutions in non-DEHP containers and administer using non-DEHP administration sets⁹
- compatible with infusion bags made of non-DEHP PVC, polyolefin, EVA, and polypropylene⁹
- due to a low extraction volume, CSTDs should not be used to withdraw botensilimab from the vial; Chemo-Vent® may be used to vent the vial. CSTDs can be used for administration.¹⁰

Compatibility: consult detailed reference

PARENTERAL ADMINISTRATION:

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

Subcutaneous	no information found
Intramuscular	no information found
Direct intravenous	no information found
<i>Intermittent infusion</i>	<i>over 30 min</i> ; use non-DEHP administration sets and 0.2 micron in-line filter ⁹
Continuous infusion	no information found
Intraperitoneal	no information found
Intrapleural	no information found
Intrathecal	no information found
Intra-arterial	no information found
Intravesical	no information found

DOSAGE GUIDELINES:

Refer to protocol by which patient is being treated.

Adults:

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

	Cycle Length:	
<i>Intravenous:</i>	2 weeks²:	<i>240 mg IV for one dose on day 1</i> (total dose per cycle 240 mg) dose escalation or reduction is not recommended ²

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3. Brest P, Mograbi B, Hofman P, et al. COVID-19 vaccination and cancer immunotherapy: should they stick together? Br J Cancer ; 2022;126(1):1–3
4. Chong C, Park VJ, Cohen B, et al. Safety of inactivated influenza vaccine in cancer patients receiving immune checkpoint inhibitors. Clin Infect Dis ; 2020;70(2):193–199
5. Desage A, Bouleftour W, Rivoirard R, et al. Vaccination and immune checkpoint inhibitors: does vaccination increase the risk of immune-related adverse events? A systematic review of literature. Am J Clin Oncol ; 2021;44(3):109–113
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7. BC Cancer Supportive Care Tumour Group. (SCNAUSEA) BC Cancer Guidelines for Prevention and Treatment of Chemotherapy-Induced Nausea and Vomiting in Adults. Vancouver, British Columbia: BC Cancer; September 1 , 2022.
8. BC Cancer Provincial Systemic Therapy Program. Provincial Systemic Therapy Program Policy III-20: Prevention and Management of Extravasation of Chemotherapy. Vancouver, British Columbia: BC Cancer; March 1 , 2021.
9. Agenus Inc. Pharmacy Manual for Botensilimab (AGEN1181) and Balstilimab (AGEN2034) Version 1.0: Expanded Access Compassionate Use Program. Lexington, MA, USA; January 27, 2026.
10. de Lemos, Mario. BC Cancer Provincial Pharmacy Professional Practice Leader and Drug Information Coordinator. SBAR: Preparing Botensilimab and Balstilimab - BC Cancer Recommendation. Vancouver, British Columbia; September 28, 2026.