The first regimen indicated for resectable muscle-invasive bladder cancer in neoadjuvant combination therapy followed by adjuvant monotherapy[1,2]*

Pr IMFINZI® durvalumab

Treatment modifications for IMFINZI® — for immune-mediated adverse reactions[1]

Adverse Reactions	Severity	IMFINZI treatment modification
Immune-mediated pneumonitis/ interstitial lung disease	Grade 2	Withhold dose*
	Grade 3 or 4	Permanently discontinue
Immune-mediated hepatitis	ALT or AST >3 – ≤5 x ULN or total bilirubin >1.5 – ≤3 x ULN	Withhold dose*
	ALT or AST >5 – ≤10 x ULN	Withhold dose*
	Concurrent ALT or AST >3 x ULN and total bilirubin >2 x ULN†	Permanently discontinue
	ALT or AST >10 x ULN or total bilirubin >3 x ULN	
Immune-mediated hepatitis in HCC (or secondary tumour involvement of the liver with abnormal baseline values)†	ALT or AST >2.5 – ≤5 x BLV and ≤20 x ULN	Withhold dose*
	ALT or AST >5 – ≤7 x BLV and ≤20 x ULN or Concurrent ALT or AST >2.5 – ≤5 x BLV and ≤20 x ULN and total bilirubin >1.5 –<2 x ULN‡	Withhold dose*
	ALT or AST >7 x BLV or >20 x ULN (whichever occurs first) or total bilirubin >3 x ULN	Permanently discontinue
Immune-mediated colitis or diarrhea	Grade 2 or 3	Withhold dose*
	Grade 4 or recurrent Grade 3	Permanently discontinue
	Intestinal perforation of ANY grade	Permanently discontinue
Immune-mediated endocrinopathies: hyperthyroidism, thyroiditis	Grade 2 – 4	Withhold dose until clinically stable
Immune-mediated endocrinopathies: hypothyroidism	Grade 2 – 4	No change
Immune-mediated endocrinopathies: adrenal insufficiency, hypophysitis/ hypopituitarism	Grade 2 – 4	Withhold dose until clinically stable
Immune-mediated endocrinopathies: Type 1 diabetes mellitus	Grade 2 – 4	No change
Immune-mediated nephritis	Grade 2 with serum creatinine >1.5 – 3 x (ULN or baseline)	Withhold dose*
	Grade 3 with serum creatinine >3 x baseline or >3 – 6 x ULN; Grade 4 with serum creatinine >6 x ULN	Permanently discontinue
Immune-mediated rash or dermatitis (including pemphigoid)	Grade 2 for >1 week or Grade 3	Withhold dose*
	Grade 4 or recurrent Grade 3	Permanently discontinue
Infection	Grade 3 or 4	Withhold dose
Immune-mediated myocarditis	Any Grade	Permanently discontinue
Immune-mediated myositis/ polymyositis/rhabdomyolysis	Grade 2 or 3	Withhold dose*§
	Grade 4 or recurrent Grade 3	Permanently discontinue
Infusion-related reactions	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue
Immune-mediated myasthenia gravis	Grade 2 – 4	Permanently discontinue
Immune-mediated encephalitis	Grade 2 – 4	Permanently discontinue
Immune-mediated Guillain- Barré syndrome	Grade 2 – 4	Permanently discontinue
Other immune-mediated adverse reactions (including immune thrombocytopenia, pancreatitis, immune- mediated arthritis, and uveitis)	Grade 2 or 3	Withhold dose*
	Grade 4 or recurrent Grade 3	Permanently discontinue

Adapted from Product Monograph[1]

Please see the product monograph for complete treatment modifications and management recommendations.

Clinical use:

The safety and efficacy of IMFINZI in patients younger than 18 years of age have not been established. Therefore, Health Canada has not authorized an indication for pediatric use.

No overall differences in safety or efficacy were reported between elderly patients (≥65 years of age) and younger patients (<65 years of age).

Most serious warnings and precautions:

Immune-mediated adverse reactions: IMFINZI as monotherapy or in combination with other products can cause severe and fatal immune-mediated adverse reactions, including enterocolitis, intestinal perforation, hepatitis, dermatitis, Stevens-Johnson syndrome, endocrinopathy, pneumonitis, interstitial lung disease, myocarditis, neuropathy, encephalitis, myasthenia gravis, as well as toxicities in other organ systems. Immune-mediated adverse reactions have occurred at higher frequencies when IMFINZI is administered as a combination therapy with tremelimumab compared with IMFINZI as monotherapy.

Other relevant warnings and precautions:

- Administer under the supervision of healthcare practitioners experienced in the treatment of cancer
- Serious embolic events in combination with gemcitabine and cisplatin
- Driving and operating machinery
- Immune-mediated adverse reactions; continuous monitoring required
- Infections
- Infusion-related reactions
- Monitoring and laboratory tests
- Fertility
- Pregnant and breast-feeding women

For more information:

Please consult the IMFINZI Product Monograph at http://www.imfinzi-en.azpm.ca/ for important information relating to adverse reactions, drug interactions, and dosing, which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-800-668-6000.

ALT: alanine aminotransferase; AST: aspartate aminotransferase; BLV: baseline value; ULN: upper limit of normal.

* After withholding, IMFINZI® can be resumed within 12 weeks if the adverse reactions improved to ≤Grade 1 and the corticosteroid dose has been reduced to ≤10 mg prednisone or equivalent per day.

† If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI® based on recommendations for hepatitis with no liver involvement.

‡ For patients with alternative cause follow the recommendations for AST or ALT increases without concurrent bilirubin elevations.

§ Permanently discontinue IMFINZI® if adverse reaction does not resolve to ≤Grade 1 within 30 days or if there are signs of respiratory insufficiency.

References:

1. IMFINZI Product Monograph. AstraZeneca Canada Inc. Feb 20, 2026.
2. Data on file. AstraZeneca Canada Inc.

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