IMFINZI®
durvalumab
50 mg/mL concentrate for solution for infusion

# MATTERHORN hospital resource pack for treatment of eligible patients with resectable GC or GOJC

**Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting www.contactazmedical.astrazeneca.com or by calling 0800 783 0033.**

IMFINZI PI

Prescribing Information for **IMFINZI** (durvalumab) can be accessed by clicking the tab on the right hand side of this slide.

This is a promotional presentation developed and funded by AstraZeneca and is intended for UK healthcare professionals only.

GC, gastric cancer; GOJC, gastro-oesophageal junction cancer.

May 2026, GB-75303

AstraZeneca

# Table of contents


1 Therapeutic indications in GC/GOJC

2 Patient initiation guidance indications

3 Dosing and administration

4 Adverse event and adverse event management


Click to be taken directly to the relevant section

GC/GOJC, gastric cancer/gastric oesophageal junction cancer.

# Therapeutic indications in GC/GOJC

**Therapeutic indications in GC/GOJC**

**Patient initiation guidance indications**

**Dosing and administration**

**Adverse event and adverse event management**

GC/GOJC, gastric cancer/gastro-oesophageal junction cancer.

# Your guide to this document

This document provides useful information that will help you administer **IMFINZI** (durvalumab) to patients for whom it has been prescribed.

## Therapeutic indication for IMFINZI in GC/GOJC*

UK

**IMFINZI** (durvalumab) in combination with **FLOT chemotherapy** as neoadjuvant and adjuvant treatment, followed by **adjuvant IMFINZI monotherapy**, is indicated for the treatment of adults with **resectable gastric or gastro-oesophageal junction adenocarcinoma.**[1]

**IMFINZI** is the **brand name of the medicine durvalumab**[1]

**For full details on the therapeutic indications of IMFINZI, please consult the SmPC for IMFINZI**[1]

*This asset will focus on the indication of IMFINZI in patients with resectable GC or GOJC.
GC/GOJC, gastric cancer/gastro-oesophageal junction cancer; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics.

# Ordering information[1,2]

| Product | Strength | EAN | PIP | List Price* |
|---|---|---|---|---|
| **IMFINZI 2.4 mL concentrate for solution for infusion vial** | 120 mg | 05000456072892 | 4090114 | £592 |
| **IMFINZI 10 mL concentrate for solution for infusion vial** | 500 mg | 05000456072847 | 4090106 | £2,466 |

Stock can be ordered via our agent, Phoenix Healthcare Distribution Ltd (customerservice@phoenixmedical.co.uk).

*This price is for hospital use only.
AAH, Amalgamated Anthracite Holdings Limited; Alliance, Alliance Healthcare; PIP, Pharmacy Item Price code.
1. IMFINZI. Summary of Product Characteristics. 2. NICE. Medicinal forms: Durvalumab. Available at: https://bnf.nice.org.uk/drugs/durvalumab-specialist-drug/medicinal-forms/. Accessed May 2026

# NICE recommends IMFINZI in combination with FLOT in patients with GC/GOJC

NICE

**NICE guidance** on **IMFINZI** in combination with **FLOT** for the treatment of adults with **resectable gastric or gastro-oesophageal junction adenocarcinoma** has been published.*[1]

* Durvalumab can only be used if the company provides it according to the commercial arrangement.
GC/GOJC, gastric cancer/gastro-oesophageal junction cancer; NICE, National Institute for Health and Care Excellence.
1. NICE. Final Draft Guidance. https://www.nice.org.uk/guidance/gid-ta11440/documents/674. Accessed May 2026.

# Patient initiation guidance indications

Therapeutic indications in GC/GOJC

**Patient initiation guidance indications**

Dosing and administration

Adverse event and adverse event management

GC/GOJC, gastric cancer/gastro-oesophageal junction cancer.

# Contraindications to IMFINZI

## Contraindications to IMFINZI[1]

Hypersensitivity to the active substance(s) or to any of the excipients listed below:

- Histidine
- Histidine hydrochloride monohydrate
- Trehalose dihydrate
- Polysorbate 80 (E 433)
- Water for injections

1. IMFINZI. Summary of Product Characteristics.

# Routine blood test requirements

**Patients should be monitored for liver, thyroid and renal function tests prior to and periodically during treatment.**[1]
**In addition, you may wish to consider local guidelines and recommendations for routine blood tests before and during treatment.**

1. IMFINZI. Summary of Product Characteristics.

# Pregnancy and lactation

## Considerations for pregnancy and lactation

- **Contraception:** Women of childbearing potential should use effective contraception during treatment with **IMFINZI** and for at least 3 months after the last dose of treatment[1]

- **Pregnancy: IMFINZI** may cause foetal harm when administered to a pregnant woman; therefore, the regimen is not recommended during pregnancy or in women of childbearing potential who are not using effective contraception during treatment and for at least 3 months after the last dose[1]

- **Breastfeeding:** It is unknown whether durvalumab is secreted in human breast milk, however, a potential risk to the breast-fed child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue or abstain from **IMFINZI** therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman[1]

**Please see section 4.6 of the IMFINZI SmPC for further information on the effect of IMFINZI on fertility, pregnancy and lactation[1]**

SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics.

# Dosing and administration

Therapeutic indications in GC/GOJC

Patient initiation guidance indications

**Dosing and administration**

Adverse event and adverse event management

GC/GOJC, gastric cancer/gastro-oesophageal junction cancer.

# Dosing[1]

- 1500 mg of **IMFINZI** in combination with FLOT chemotherapy every 4 weeks for up to 2 cycles prior to surgery, followed by 1500 mg of **IMFINZI**, with FLOT chemotherapy, every 4 weeks for up to 2 cycles and then 1500 mg of **IMFINZI** monotherapy every 4 weeks for up to 10 cycles, for a total of up to 12 cycles after surgery for the treatment of adults with resectable GC/GOJC.
  - The neoadjuvant phase of treatment may continue until disease progression that precludes definitive surgery or unacceptable toxicity, or for a maximum of 2 cycles prior to surgery.
  - The adjuvant phase of treatment may continue until progression or recurrence, unacceptable toxicity, or for a maximum of 12 cycles after surgery.
- GC/GOJC patients with a body weight of 30 kg or less must receive weight-based dosing of **IMFINZI** at 20 mg/kg.
- Dose escalation or reduction is not recommended. Treatment withholding or discontinuation may be required based on individual safety and tolerability.
- Guidelines for management of immune-mediated and non-immune mediated adverse reactions are described in table 2 of section 4.2 of the SmPC, and further information is given in section 4.4 of the SmPC

SmPC, summary of product characteristics; GC/GOJC, gastric cancer/gastro-oesophageal junction cancer.

1. IMFINZI. Summary of Product Characteristics.

# Administration[1]

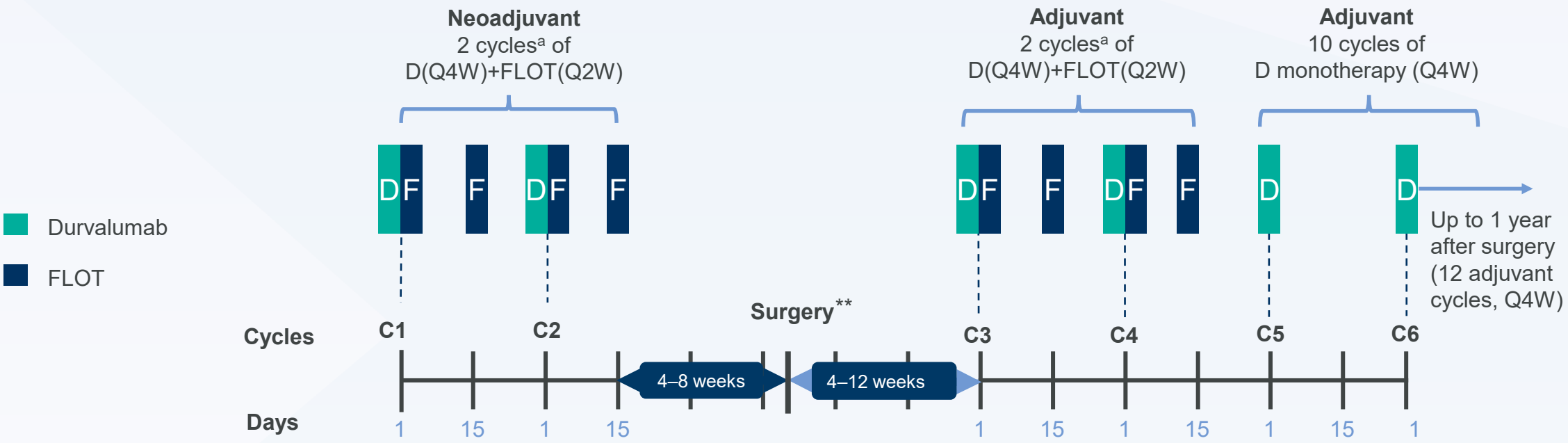
- When **IMFINZI** is administered in combination with chemotherapy, administer **IMFINZI** prior to chemotherapy on the same day.
- Administer the infusion solution intravenously over 60 minutes through an intravenous line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter
- Do not co-administer other medicinal products through the same infusion line
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements

SmPC, summary of product characteristics; GC/GOJC, gastric cancer/gastro-oesophageal junction cancer.

1. IMFINZI. Summary of Product Characteristics.

# Treatment sequence of IMFINZI in combination with FLOT[1,2]

**Neoadjuvant therapy:** Up to 2 cycles of durvalumab 1500 mg* (Q4W) + 4 cycles of FLOT (Q2W)
**Adjuvant therapy:** Up to 2 cycles of durvalumab 1500 mg* (Q4W) + 4 cycles of FLOT (Q2W) followed by up to 10 cycles of durvalumab




**Dose escalation or reduction is not recommended.**
**Treatment withholding or discontinuation may be required based on individual safety and tolerability**[1]

***GC/GOJC patients with a body weight of 30 kg or less must receive weight-based dosing of IMFINZI at 20 mg/kg. **Surgery timings based on MATTERHORN study schedule.**
[a]One cycle comprises of 1 dose of IV durvalumab (1500 mg) and 2 doses of FLOT.
C, cycle; D, durvalumab; F, FLOT; FLOT, 5-fluorouracil, leucovorin, oxaliplatin, docetaxel; P, placebo; Q2W, every 2 weeks; Q4W, every 4 weeks.
1. IMFINZI. Summary of Product Characteristics.. 2. Janjigian YY, Van Cutsem E, Muro K, et al. MATTERHORN: phase III study of durvalumab plus FLOT chemotherapy in resectable gastric/gastro-oesophageal junction cancer. Future Oncol. 2022;18:2465–2473.

# Preparation and handling of IMFINZI[1]

**IMFINZI is supplied as a single-dose vial that does not contain any preservatives, aseptic technique must be observed**

**Visually inspect the medicinal product IMFINZI for particulate matter and discolouration**

**IMFINZI is a clear to opalescent, colourless to slightly yellow solution.** Discard the vial if the solution is cloudy, discoloured or visible particles are observed. Do not shake the vial.

**Handling instructions for IMFINZI**

- Withdraw the required volume from the vial(s) of **IMFINZI** and transfer into an intravenous bag containing sodium chloride 9 mg/mL (0.9%) solution for injection, or glucose 50 mg/mL (5%) solution for injection
- Mix diluted solution by gentle inversion. The final concentration of the diluted solution should be between 1 mg/mL and 15 mg/mL
- Do not freeze or shake the solution
- Discard any unused portion left in the vial
- Do not co-administer other medicinal products through the same infusion line

1. IMFINZI. Summary of Product Characteristics.

# Shelf life and storage conditions

## Shelf life of IMFINZI[1]

IMFINZI® durvalumab 50 mg/mL concentrate for solution for infusion

### Unopened vial:

- **3 years**

### Special precautions for storage:

- **Store in a refrigerator (2°C to 8°C)**
- **Do not freeze**
- **Store in the original package in order to protect from light.**

### Diluted solution:

- **Chemical and physical** in-use stability has been demonstrated **for up to 30 days** at **2–8 °C** and for up to **24 hours** at **room temperature** (up to 25 °C) from the time of preparation

From a microbiological point of view, the prepared solution for infusion for infusion should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2–8 °C or 12 hours at room temperature (up to 25 °C), unless dilution has taken place in controlled and validated aseptic conditions[1]

1. IMFINZI. Summary of Product Characteristics.

# Adverse event and adverse event management

Therapeutic indications in GC/GOJC

Patient initiation guidance indications

Dosing and administration

**Adverse event and adverse event management**

GC/GOJC, gastric cancer/gastro-oesophageal junction cancer.

# Introduction to AEs and AE management

**The most common AEs reported in >10% of patients treated with IMFINZI in combination with chemotherapy, based on pooled data in 2,244 patients from 6 studies[1]**

- Neutropenia (44.6%)
- Nausea (42.4%)
- Fatigue (41.2%)
- Anaemia (37.4%)
- Diarrhoea (27.5%)
- Constipation (26.7%)
- Decreased appetite (24.0%)
- Alopecia (22.0%)
- Neuropathy peripheral (21.6%)
- Rash (21.0%)
- Thrombocytopenia (19.7%)
- Vomiting (18.8%)
- Abdominal pain (17.9%)
- Pyrexia (15.2%)
- Leukopenia (14.9%)
- Pruritus (12.5%)
- Hypothyroidism (11.1%)
- Arthralgia (10.9%)
- Cough/productive cough (10.8%)
- Aspartate aminotransferase increased/alanine aminotransferase increased (10.5%)

**IMFINZI is associated with imAEs. Routine monitoring of patients for signs and symptoms is advised[1]**

- The use of systemic corticosteroids or immunosuppressants before starting IMFINZI, except physiological dose of systemic corticosteroids (≤10 mg/day prednisone or equivalent), is not recommended because of their potential interference with the pharmacodynamic activity and efficacy of IMFINZI[1]
- However, systemic corticosteroids or other immunosuppressants can be used after starting IMFINZI to treat imAEs (see section 4.4 of the SmPC for IMFINZI)[1]

AE, adverse event; imAE, immune-mediated adverse event; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics.

# Summary of adverse events in the MATTERHORN safety analysis population[1]

| Adverse Event | Durvalumab plus FLOT (N = 475)* | Placebo plus FLOT (N = 469) |
|---|---|---|
| Any grade | 471 (99.2) | 463 (98.7) |
| Possibly related to any trial treatment | 453 (95.4) | 444 (94.7) |
| Maximum grade 3 or 4 adverse event | 340 (71.6) | 334 (71.2) |
| Possibly related to any trial treatment | 283 (59.6) | 277 (59.1) |
| Serious adverse event | 229 (48.2) | 207 (44.1) |
| Adverse event leading to discontinuation of any trial regimen | 142 (29.9) | 107 (22.8) |
| Leading to discontinuation of durvalumab or placebo | 48 (10.1) | 30 (6.4) |
| Leading to discontinuation of any component of FLOT | 121 (25.5) | 95 (20.3) |
| Adverse event with outcome of death | 24 (5.1) | 20 (4.3) |
| Possibly related to durvalumab or placebo | 3 (0.6) | 1 (0.2) |
| Possibly related to FLOT | 3 (0.6) | 2 (0.4) |
| Immune-mediated adverse event of any grade** | 110 (23.2) | 34 (7.2) |
| Any adverse event leading to surgery not being performed | 3 (0.6) | 2 (0.4) |
| Any adverse event leading to a delay in surgery*** | 11 (2.3) | 12 (2.6) |
| Any adverse event possibly related to surgery | 182 (38.3) | 173 (36.9) |

* One participant in the placebo group received a single  of durvalumab and was therefore included in the durvalumab group for the safety analysis.
** This category excludes infusion or hypersensitivity reactions
*** A surgical delay was defined as surgery occurring more than 8 weeks (56 days) after the last dose of neoadjuvant treatment

Table adapted from Janjigian et al, 2025
FLOT, 5-fluorouracil, leucovorin, oxaliplatin, docetaxel.

1. Janjigian YY, Al-Batran SE, Wainberg ZA, et al; MATTERHORN Investigators. Perioperative Durvalumab in Gastric and Gastroesophageal Junction Cancer. New England Journal of Medicine. 2025 July 17;393(3):217-230. doi: 10.1056/NEJMoa2503701

# Summary of the most common adverse events occurring in either group of the MATTERHORN safety analysis population[1]

| Adverse Event | Durvalumab plus FLOT (N = 475)* | Placebo plus FLOT (N = 469) |
|---|---|---|
| **Most common adverse events of any grade occurring in ≥30% of participants in either group** | | |
| Diarrhoea | 296 (62.3) | 270 (57.6) |
| Nausea | 241 (50.7) | 237 (50.5) |
| Neutropenia | 153 (32.2) | 155 (33.0) |
| Alopecia | 145 (30.5) | 149 (31.8) |
| Decreased appetite | 145 (30.5) | 141 (30.1) |
| Fatigue | 137 (28.8) | 146 (31.1) |
| Anaemia | 119 (25.1) | 147 (31.3) |
| **Most common adverse events of maximum grade 3 or 4 occurring in ≥5% of participants in either group** | | |
| Neutropenia | 101 (21.3) | 104 (22.2) |
| Neutrophil count decreased | 93 (19.6) | 105 (22.4) |
| Diarrhoea | 30 (6.3) | 29 (6.0) |
| White-cell count decreased | 25 (5.3) | 28 (6.0) |
| Anaemia | 24 (5.1) | 24 (5.1) |

* One participant in the placebo group received a single of durvalumab and was therefore included in the durvalumab group for the safety analysis

Table adapted from Janjigian et al, 2025
FLOT, 5-fluorouracil, leucovorin, oxaliplatin, docetaxel.

1. Janjigian YY, Al-Batran SE, Wainberg ZA, et al; MATTERHORN Investigators. Perioperative Durvalumab in Gastric and Gastroesophageal Junction Cancer. New England Journal of Medicine. 2025 July 17;393(3):217-230. doi: 10.1056/NEJMoa2503701.

# Summary of immune-mediated adverse events occurring in either group of the MATTERHORN safety analysis population[1]

| Adverse Event | Durvalumab plus FLOT (N = 475) | Placebo plus FLOT (N = 469) |
|---|---|---|
| Immune mediated adverse event of any grade* | 110 (23.2) | 34 (7.2) |
| Maximum grade 3 or 4 immune-mediated adverse event | 34 (7.2) | 17 (3.6) |
| Serious immune-mediated adverse event, including events with outcome of death | 23 (4.8) | 13 (2.8) |
| Immune-mediated adverse event, including events with outcome of death | 2 (0.4) | 0 |

* This category excludes infusion or hypersensitivity reactions.

Table adapted from Janjigian et al, 2025
FLOT, 5-fluorouracil, leucovorin, oxaliplatin, docetaxel.

1. Janjigian YY, Al-Batran SE, Wainberg ZA, et al; MATTERHORN Investigators. Perioperative Durvalumab in Gastric and Gastroesophageal Junction Cancer. New England Journal of Medicine. 2025 July 17;393(3):217-230. doi: 10.1056/NEJMoa2503701.

# Adverse event reporting

**Adverse event reporting information**

**Adverse events should be reported.** Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. **Adverse events should also be reported to AstraZeneca** by visiting www.contactazmedical.astrazeneca.com or by calling 0800 783 0033

# Warnings and precautions (1/3)

## Special warning and precautions for use

- **Traceability:** In order to improve the traceability of biological medicinal products, the tradename and the batch number of the administered product should be clearly recorded[1]

- **Pneumonitis and immune-mediated pneumonitis:** Monitor for signs and symptoms of pneumonitis, immune-mediated pneumonitis, radiation pneumonitis, or interstitial lung disease.[1]

- **Immune-mediated hepatitis:** Monitor alanine aminotransferase, aspartate aminotransferase, total bilirubin, and alkaline phosphatase levels prior to initiation of treatment and prior to each subsequent infusion. Additional monitoring is to be considered based on clinical evaluation[1]

- **Immune-mediated colitis/diarrhoea:** Monitor for signs and symptoms of colitis/diarrhoea and intestinal perforation[1]

- **Immune-mediated endocrinopathies:**
  - Monitor thyroid function tests associated with hypothyroidism, hyperthyroidism, and thyroiditis prior to and periodically during treatment and as indicated based on clinical evaluation[1]
  - Monitor for clinical signs and symptoms of adrenal insufficiency, Type 1 diabetes mellitus, and hypophysitis or hypopituitarism[1,2]

**All AEs should be managed as recommended in section 4.2 of the IMFINZI SmPC**

**Please see section 4.4 of the IMFINZI SmPC for further information on the special warning and precautions for use**

imAE, immune-mediated adverse reaction; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics.

# Warnings and precautions (2/3)

## Special warning and precautions for use

- **Immune-mediated nephritis:** Monitor renal function tests prior to and periodically during treatment[1]

- **Immune-mediated rash/dermatitis:** Events of Stevens–Johnson Syndrome or toxic epidermal necrolysis have been reported in patients treated with PD-1 inhibitors.[1] Patients should be monitored for signs and symptoms of rash or dermatitis[1]

- **Immune-mediated myocarditis:** Immune-mediated myocarditis, which can be fatal, occurred in patients receiving **IMFINZI** (see section 4.8 of the **IMFINZI** SmPC).[1] Patients should be monitored for signs and symptoms of immune-mediated myocarditis[1]

- **Other immune-mediated adverse reactions:** Monitor for signs and symptoms of myasthenia gravis, transverse myelitis, myositis, polymyositis, rhabdomyolysis, meningitis, encephalitis, Guillain-Barré syndrome, immune thrombocytopenia, immune-mediated arthritis, uveitis, noninfective cystitis, polymyalgia rheumatica and pancreatitis (see section 4.8 of the **IMFINZI** SmPC)[1]

- **Patients with pre-existing autoimmune disease:** In patients with pre-existing autoimmune disease (AID), data from observational studies suggest an increased risk of immune-related adverse reactions following immune-checkpoint inhibitor therapy as compared with patients without pre-existing AID. In addition, flares of the underlying AID were frequent, but the majority were mild and manageable[1]

- **Infusion-related reactions:** Monitor for signs and symptoms of infusion-related reactions[1]

**All AEs should be managed as recommended in section 4.2 of the IMFINZI SmPC**

**Please see section 4.4 of the IMFINZI SmPC for further information on the special warning and precautions for use**[1]

imAE, immune-mediated adverse event; PD-1, programmed cell death protein 1; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics.

# Warnings and precautions (3/3)

## Special warning and precautions for use[1,2]

Patients with resectable GC/GOJC with any of the following were excluded from the MATTERHORN clinical trial:[1]

- Peritoneal spread, distant metastasis, or excluded tumour types (e.g., ASCC, SCC, GIST)
- History of allogeneic organ transplant or primary immunodeficiency
- Active / prior documented autoimmune or inflammatory disorders (with specific exceptions)
- Uncontrolled intercurrent illness or ongoing or active infections (including TB, HBV, HCV, HIV)
- Prior malignancy (unless treated with curative intent and with no active disease within ≥5 years and low risk of recurrence, or certain adequately treated in situ / skin cancers)
- Allergies or hypersensitivities to programme drugs or components
- Ongoing cancer treatments or prior immune-mediated therapy
- Recent or ongoing immunosuppressive therapy (with limited exceptions)
- Recent or concurrent participation in interventional clinical trials
- Pregnancy,* breastfeeding, inadequate contraception, or physician deems patient unsuitable

In the absence of data, **IMFINZI should be used with caution in these populations** after careful consideration of the potential benefit/risk on an individual basis[3]

**Please refer to the IMFINZI SmPC for the complete safety profile, special warnings and precautions for use[3]**

* IMFINZI is not recommended during pregnancy.

ASCC, adenosquamous cell carcinoma; GC/GOJC, gastric cancer/gastro-oesophageal junction cancer; GIST, gastrointestinal stromal tumour; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; SCC, squamous cell carcinoma; SmPC, summary of product characteristics; TB, tuberculosis.

1. Janjigian YY, Al-Batran SE, Wainberg ZA, et al; MATTERHORN Investigators. Perioperative Durvalumab in Gastric and Gastroesophageal Junction Cancer. New England Journal of Medicine. 2025 July 17;393(3):217-230. doi: 10.1056/NEJMoa2503701. 2. Protocol for Janjigian YY, Al-Batran SE, Wainberg ZA, et al; MATTERHORN Investigators. Perioperative Durvalumab in Gastric and Gastroesophageal Junction Cancer. New England Journal of Medicine. 2025 July 17;393(3):217-230. doi: 10.1056/NEJMoa2503701. 3. IMFINZI. Summary of Product Characteristics.

## Confidentiality Notice

This file is private and may contain confidential and proprietary information. If you have received this file in error, please notify us and remove it from your system and note that you must not copy, distribute or take any action in reliance on it. Any unauthorised use or disclosure of the contents of this file is not permitted and may be unlawful. AstraZeneca PLC, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA, UK, T: +44(0)203 749 5000, www.astrazeneca.com