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

IMJUDO®▼
tremelimumab
20 mg/mL concentrate for solution for infusion

HIMALAYA hospital resource pack for treatment of eligible patients with advanced or unresectable HCC

IMFINZI PI

IMJUDO PI

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.

Prescribing Information for IMFINZI (durvalumab) and IMJUDO▼ (tremelimumab) can be accessed by clicking the tabs on the right hand side of this slide and can also be found at the end of this presentation.

This presentation is developed and funded by AstraZeneca.

HCC, hepatocellular carcinoma.

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GB-72998

For UK healthcare professionals only.

AstraZeneca

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HCC, hepatocellular carcinoma.

Therapeutic indications in HCC

Therapeutic indications in HCC | **Patient initiation guidance indications** | **Dosing and administration** | **Adverse event and adverse event management**

HCC, hepatocellular carcinoma.

Your guide to this document

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

Therapeutic indication for IMFINZI in combination with IMJUDO*

IMFINZI (durvalumab) in combination with **IMJUDO** (tremelimumab) is indicated for the **first-line treatment** of **adults** with **advanced or unresectable HCC**[1,2]

UK

This therapeutic combination **constitutes the STRIDE regimen** (Single Tremelimumab Regular Interval Durvalumab)[3]

IMFINZI is the **brand name of the medicine durvalumab**[1]
IMJUDO is the **brand name of the medicine tremelimumab**[2]

For full details on the therapeutic indications, please consult the SmPCs for IMFINZI and IMJUDO[1,2]

*This asset will focus on the indication of IMFINZI and IMJUDO▼ in patients with advanced or unresectable HCC.
HCC, hepatocellular carcinoma; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025;
3. Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070.

Ordering information[1–5]

Product	Strength	Link Code (AAH)	PIP Code (Alliance)	List Price*
IMFINZI 2.4 mL concentrate for solution for infusion vial	120 mg	IMF0006B	4090114	£592
IMFINZI 10 mL concentrate for solution for infusion vial	500 mg	IMF0007U	4090106	£2,466
IMJUDO 15 mL concentrate for solution for infusion vial	300 mg	IMJ0001G	5401500	£20,610

*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. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025;
3. NICE. Medicinal forms: Durvalumab. Available at: https://bnf.nice.org.uk/drugs/durvalumab-specialist-drug/medicinal-forms/. Accessed December 2025;
4. NICE. Medicinal forms: Tremelimumab. Available at: https://bnf.nice.org.uk/drugs/tremelimumab-specialist-drug/. Accessed December 2025;
5. AstraZeneca. Data on File 2025.

IMJUDO ordering process

Overall ordering process for IMJUDO[1–3]

Weekly ordering schedule:[1,2]

Order before 12 noon	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Delivery day	Tuesday	Wednesday	Thursday	Friday	Saturday*	Monday	Tuesday

Any queries, please contact: supply.chain@astrazeneca.com
Phoenix escalation (National Hospital Sales Manager): shaywood@phoenixmedical.co.uk

*If Saturday delivery services are offered.

1. ProCure+. Imjudo (tremelimumab) Ordering Process. Available at: https://intercom-help.eu/ProCure/en/articles/235903-imjudo-tremelimumab-ordering-process. Accessed December 2025;
2. AstraZeneca. Data on File 2025; 3. Phoenix Medical Supplies Limited. New state-of-the-art distribution hub in Wakefield. Available at: https://www.phoenixmedical.co.uk/en/news-updates/news-updates-solo/new-state-of-the-art-distribution-hub-in-wakefield. Accessed December 2025.

NICE and SMC recommend IMFINZI in combination with IMJUDO in patients with uHCC

NICE

NICE guidance on **IMFINZI** in combination with **IMJUDO** for the **first-line treatment** of adults with **advanced or unresectable HCC** has been published[1]

SMC

SMC guidance on **IMFINZI** in combination with **IMJUDO** for the **first-line treatment** of adults with **advanced or unresectable HCC** has been published[2]

HCC, hepatocellular carcinoma; NICE, National Institute for Health and Care Excellence; SMC, Scottish Medicines Consortium.

1. NICE. Durvalumab with tremelimumab for untreated advanced or unresectable hepatocellular carcinoma [ID2725]. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ta10571. Accessed December 2025; 2. SMC. Durvalumab (IMFINZI). Available at: https://scottishmedicines.org.uk/medicines-advice/durvalumab-imfinzi-full-smc2735/. Accessed December 2025.

Patient initiation guidance indications

Therapeutic indications in HCC | **Patient initiation guidance indications** | Dosing and administration | Adverse event and adverse event management

HCC, hepatocellular carcinoma.

Contraindications to IMFINZI and IMJUDO

Contraindications to IMFINZI and IMJUDO[1,2]

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
- Disodium edetate dihydrate **(IMJUDO only)**

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

IMJUDO®▼ tremelimumab 20 mg/mL concentrate for solution for infusion

*IMFINZI only.[1]

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Routine blood test requirements

Patients should be monitored for abnormal thyroid and renal function tests prior to and periodically during treatment.[1,2]

In addition, you may wish to consider local guidelines and recommendations for routine blood tests before and during treatment[3,4]

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025; 2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025; 3. CRUK. Durvalumab (Imfinzi). Available at: https://www.cancerresearchuk.org/aboutcancer/treatment/drugs/durvalumab#:~:text=You%20have%20blood%20tests%20before,liver%20and%20kidneys%20are%20working. Accessed December 2025; 4. Kelley RK. Durvalumab Plus Tremelimumab for First-Line Treatment of Hepatocellular Carcinoma. Gastroenterol Hepatol (N Y). 2024;20(2):119–122.

Dosing and administration

Therapeutic indications in HCC | Patient initiation guidance indications | **Dosing and administration** | Adverse event and adverse event management

HCC, hepatocellular carcinoma.

Dosing and administration (1/2)

For uHCC, administer IMJUDO prior to IMFINZI on the same day as separate intravenous infusions[1,2]

- 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; uHCC, unresectable hepatocellular carcinoma.

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Dosing and administration (2/2)

STRIDE regimen: single priming dose of IMJUDO + IMFINZI on Day 1, followed by IMFINZI every 4 weeks

For patients with body weight >40 kg[1–4]

No premedication needed

A **single priming dose** of **300 mg IMJUDO** is given as an **intravenous infusion*** over **60 minutes**

A **separate intravenous infusion** of **1500 mg IMFINZI†** is then given over **60 minutes**

Following **blood tests** to monitor for certain **side effects**, patients will **return home**

Treatment with **1500 mg IMFINZI** will continue as monotherapy at a **fixed dose** via **infusion every 4 weeks** until **disease progression** or **unacceptable toxicity**

***Patients with a body weight of ≤40 kg must receive weight-based dosing equivalent to 4 mg/kg of IMJUDO, until body weight is >40 kg.**[1,2]
†**Patients with a body weight of ≤30 kg must receive weight-based dosing equivalent to 20 mg/kg of IMFINZI, until body weight is >30 kg.**[1,2]
STRIDE, Single Tremelimumab Regular Interval Durvalumab.

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025; 3. IMFINZI. How are IMFINZI + IMJUDO given? Available at: https://www.imfinzi.com/hepatocellular-carcinoma/treatment/taking-imfinzi.html. Accessed December 2025; 4. NHS. Chemotherapy. Available at: https://www.nhs.uk/conditions/chemotherapy/what-happens/. Accessed December 2025.

Duration of treatment with IMFINZI in combination with IMJUDO

Dose escalation or reduction is not recommended.
Treatment withholding or discontinuation may be required based on individual safety and tolerability[1,2]

Advanced or unresectable HCC

- **IMFINZI 1500 mg** administered in combination with **IMJUDO 300 mg** as a single dose at Cycle 1/Day 1, followed by **IMFINZI** monotherapy every 4 weeks
- Until disease progression or until unacceptable toxicity

Patients with HCC with a body weight of 30 kg or less must receive weight-based dosing, equivalent to **IMFINZI 20 mg/kg** until weight is greater than 30 kg.

Patients with a body weight of 40 kg or less must receive weight-based dosing, equivalent to **IMJUDO 4 mg/kg** until weight is greater than 40 kg.

Please refer to the full SmPCs for IMFINZI and IMJUDO for other indications

HCC, hepatocellular carcinoma; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Preparation and handling of IMFINZI and IMJUDO[1,2]

IMFINZI and IMJUDO are each supplied as a single-dose vial that does not contain any preservatives, aseptic technique must be observed

Visually inspect the medicinal product IMFINZI and IMJUDO for particular 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

IMJUDO is clear to slightly 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 and IMJUDO

- 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

- Withdraw the required volume from the vial(s) of **IMJUDO** 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 0.1 mg/mL and 10 mg/mL
- Do not freeze or shake the solution
- Discard any unused portion left in the vial
- Care must be taken to ensure the sterility of the prepared solution
- Do not re-enter the vial after withdrawal of the medicinal product
- Do not co-administer other medicinal products through the same infusion line

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Shelf life and storage conditions

Shelf life of IMFINZI[1]

Unopened vial:

- **3 years**

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

Shelf life of IMJUDO[2]

Unopened vial:

- **4 years at 2–8 °C**

Diluted solution:

- **Chemical and physical** in-use stability has been demonstrated for **up to 28 days** at **2–8 °C** and for up to **48 hours** at **room temperature** (up to 25 °C) from the time of preparation
- **Lack of microbial growth** in the prepared solution for infusion has been demonstrated for **up to 28 days** at **2–8 °C** and for **up to 48 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 **IMFINZI** and **IMJUDO** 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[1,2]

Special precautions for storage of IMFINZI and IMJUDO[1,2]

Store in a refrigerator (2–8 °C)

Do not freeze

Store in the original package in order to protect from light

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Adverse event and adverse event management

Therapeutic indications in HCC | Patient initiation guidance indications | Dosing and administration | **Adverse event and adverse event management**

HCC, hepatocellular carcinoma.

Introduction to AEs and AE management

The most common AEs reported in >10% of patients treated with IMFINZI and IMJUDO[1,2]

- Rash (32.5%)
- Pruritus (25.5%)
- Diarrhoea (25.3%)
- Abdominal pain (19.7%)
- Aspartate aminotransferase increased/alanine aminotransferase increased (18.0%)
- Pyrexia (13.9%)
- Hypothyroidism (13.0%)
- Cough/productive cough (10.8%)
- Oedema peripheral (10.4%)
- Lipase increased (10.0%)

IMFINZI and IMJUDO are associated with imAEs. Routine monitoring of patients for signs and symptoms is advised[1,2]

- The use of systemic corticosteroids or immunosuppressants before starting IMFINZI and IMJUDO, 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 and IMJUDO
- However, systemic corticosteroids or other immunosuppressants can be used after starting IMFINZI and IMJUDO to treat imAEs (see section 4.4 of the respective SmPCs for IMFINZI and IMJUDO)[1,2]

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

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Summary of treatment-emergent adverse events in the HIMALAYA safety analysis population[1]

Treatment-emergent adverse events of any cause*[1]

Event	STRIDE (n=388)	Sorafenib (n=374)
Treatment-emergent adverse events of any cause, n (%)		
Any	378 (97.4)	357 (95.5)
Any serious	157 (40.5)	111 (29.7)
Any Grade 3 or 4	196 (50.5)	196 (52.4)
Leading to discontinuation	53 (13.7)	63 (16.8)
Leading to dose delay	134 (34.5)	178 (47.6)
Leading to death	30 (7.7)	27 (7.2)
Immune-mediated requiring high-dose steroids	78 (20.1)	7 (1.9)
Any Grade 3 or 4 immune-mediated	49 (12.6)	9 (2.4)
Immune-mediated leading to death	6 (1.5)	0 (0.0)
Any Grade 3 or 4 hepatic SMQ	54 (13.9)	39 (10.4)

STRIDE offers a generally well-tolerated treatment option with lower discontinuation rates vs sorafenib[1-3]

*Table adapted from Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070.[1]
SMQ, Standardised MedDRA Query; STRIDE, Single Tremelimumab Regular Interval Durvalumab.
1. Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070; 2. Rimassa L, et al. Presented at ESMO 2024; 13–17 September. Barcelona, Spain, Abstract #947MO; 3. Lau G, et al. Poster presented at American Society of Clinical Oncology Annual Meeting; June 2-6, 2023; Chicago, IL.

Summary of the types of TEAEs in the HIMALAYA safety analysis population

TEAEs that occurred in ≥10% of patients or Grade 3 or 4 TEAEs that occurred in ≥2% of patients in any treatment arm in the safety analysis population*

	STRIDE (n=388)		Sorafenib (n=374)	
Event, n (%)	**Any Grade**	**Grade 3 or 4**	**Any Grade**	**Grade 3 or 4**
Diarrhoea	103 (26.5)	17 (4.4)	167 (44.7)	16 (4.3)
Constipation	36 (9.3)	0 (0.0)	35 (9.4)	0 (0.0)
Abdominal pain	46 (11.9)	5 (1.3)	63 (16.8)	12 (3.2)
Nausea	47 (12.1)	0 (0.0)	53 (14.2)	0 (0.0)
Pruritus	89 (22.9)	0 (0.0)	24 (6.4)	1 (0.3)
Rash	87 (22.4)	6 (1.5)	51 (13.6)	4 (1.1)
Alopecia	2 (0.5)	0 (0.0)	53 (14.2)	0 (0.0)
Palmar-plantar erythrodysesthesia syndrome	3 (0.8)	0 (0.0)	174 (46.5)	34 (9.1)
Aspartate aminotransferase increased	48 (12.4)	20 (5.2)	24 (6.4)	12 (3.2)
Alanine aminotransferase increased	36 (9.3)	10 (2.6)	20 (5.3)	7 (1.9)
Amylase increased	29 (7.5)	14 (3.6)	10 (2.7)	4 (1.1)
Blood bilirubin increased	20 (5.2)	3 (0.8)	29 (7.8)	8 (2.1)
Gamma-glutamyltransferase increased	18 (4.6)	8 (2.1)	19 (5.1)	7 (1.9)
Lipase increased	34 (8.8)	24 (6.2)	15 (4.0)	11 (2.9)
Decreased appetite	66 (17.0)	5 (1.3)	67 (17.9)	3 (0.8)
Asthenia	39 (10.1)	7 (1.8)	44 (11.8)	10 (2.7)
Fatigue	66 (17.0)	8 (2.1)	71 (19.0)	11 (2.9)
Pyrexia	50 (12.9)	1 (0.3)	33 (8.8)	0 (0.0)
Oedema peripheral	33 (8.5)	2 (0.5)	19 (5.1)	0 (0.0)
Cough	30 (7.7)	0 (0.0)	22 (5.9)	1 (0.3)
Insomnia	40 (10.3)	1 (0.3)	16 (4.3)	0 (0.0)
Hypothyroidism	47 (12.1)	0 (0.0)	16 (4.3)	0 (0.0)
Hypertension	23 (5.9)	7 (1.8)	68 (18.2)	23 (6.1)
Anaemia	36 (9.3)	11 (2.8)	33 (8.8)	12 (3.2)
Hyperkalaemia	20 (5.2)	6 (1.5)	13 (3.5)	9 (2.4)
Hypokalaemia	13 (3.4)	4 (1.0)	12 (3.2)	2 (0.5)
Hyponatraemia	21 (5.4)	16 (4.1)	15 (4.0)	11 (2.9)

*Table adapted from Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070.
STRIDE, Single Tremelimumab Regular Interval Durvalumab; TEAE, treatment-emergent adverse event.
Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070.

Immune-mediated adverse events reported at primary analysis of the HIMALAYA trial*

Event, n (%)	STRIDE (n=388)	Sorafenib (n=374)
Any immune-mediated adverse event	139 (35.8)	30 (8.0)
Any Grade 3 or 4 immune-mediated adverse event	49 (12.6)	9 (2.4)
Any serious immune-mediated adverse event	41 (10.6)	4 (1.1)
Any immune-mediated adverse event leading to death	6 (1.5)	0 (0.0)
Treatment-related immune-mediated adverse events		
Any immune-mediated adverse event	134 (34.5)	21 (5.6)
Any Grade 3 or 4 immune-mediated adverse event	49 (12.6)	9 (2.4)
Any serious immune-mediated adverse event	41 (10.6)	4 (1.1)
Any immune-mediated adverse event leading to death	6 (1.5)	0 (0.0)
Immune-mediated adverse events requiring high-dose steroids		
Any immune-mediated adverse event	78 (20.1)	7 (1.9)
Immune-mediated adverse events leading to discontinuation		
Any immune-mediated adverse event	22 (5.7)	6 (1.6)

Overall, the most common imAEs were hepatic events, diarrhoea/colitis and dermatitis/rash

*Table adapted from Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070. Supplementary Appendix.
imAE, immune-mediated adverse event; STRIDE, Single Tremelimumab Regular Interval Durvalumab.
Abou-Alfa GK, et al. *NEJM Evid*. 2022;1(8):EVIDoa2100070. Supplementary Appendix.

Patient alert card

The IMJUDO patient alert card supports patients and carers in understanding the risk of imAEs and helps them recognise, act on and report relevant symptoms.
Patients should carry this card at all times, even after discontinuing treatment, and present it to HCPs involved in their care

To access the IMJUDO patient card click here

HCP, healthcare professional; imAE, immune-mediated adverse event.
IMJUDO. Patient Card. Available at: https://www.medicines.org.uk/emc/product/14841/rmms#about-medicine. Accessed December 2025.

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

Pregnancy and lactation

Considerations for pregnancy and lactation

- **Contraception:** Women of childbearing potential should use effective contraception during treatment with **IMFINZI** and **IMJUDO** and for at least 3 months after the last dose of treatment[1,2]

- **Pregnancy:** **IMFINZI** and **IMJUDO** 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[1,2]

- **Breastfeeding:** 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]
- Breastfeeding should be discontinued during treatment with **IMJUDO** and for at least 3 months after the last dose[2]

Please see section 4.6 of the individual SmPCs for further information on the effect of IMFINZI and IMJUDO on fertility, pregnancy and lactation[1,2]

SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

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[1,2]

- **Immune-mediated pneumonitis:** Monitor for signs and symptoms of pneumonitis or radiation pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging and other infectious and disease-related aetiologies excluded[1,2]

- **Immune-mediated hepatitis:** Monitor for 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[1,2]

- **Immune-mediated colitis:** Monitor for signs and symptoms of colitis/diarrhoea and intestinal perforation[1,2]

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

All imAEs should be managed as recommended in section 4.2 of the individual SmPCs for IMFINZI and IMJUDO

Please see section 4.4 of the individual SmPCs for further information on the special warning and precautions for use of IMFINZI and IMJUDO[1,2]

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

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Warnings and precautions (2/3)

Special warning and precautions for use

- **Immune-mediated nephritis:** Monitor for abnormal renal function tests prior to, and periodically during, treatment with **IMFINZI** in combination with **IMJUDO**[1,2]

- **Immune-mediated rash:** Events of Stevens–Johnson Syndrome or toxic epidermal necrolysis have been reported in patients treated with PD-1 and CTLA-4 inhibitors.[1,2] Patients should be monitored for signs and symptoms of rash or dermatitis[1,2]

- **Immune-mediated myocarditis:** Immune-mediated myocarditis, which can be fatal, occurred in patients receiving **IMFINZI** in combination with **IMJUDO** (see section 4.8 of the individual SmPCs).[1,2] Patients should be monitored for signs and symptoms of immune-mediated myocarditis[1,2]

- **Other immune-mediated adverse reactions:** Monitor for signs and symptoms of myasthenia gravis, myositis, polymyositis, meningitis, encephalitis, Guillain–Barré syndrome, immune thrombocytopenia, cystitis noninfective, immune-mediated arthritis and uveitis (see section 4.8 of the IMJUDO SmPC)[2]

- **Infusion-related reactions:** Monitor for signs and symptoms of infusion related reactions[1,2]

All imAEs should be managed as recommended in section 4.2 of the individual SmPCs for IMFINZI and IMJUDO

Please see section 4.4 of the individual SmPCs for further information on the special warning and precautions for use of IMFINZI and IMJUDO[1,2]

CTLA-4, cytotoxic T-lymphocyte-associated protein 4; imAE, immune-mediated adverse event; PD-1, programmed cell death protein 1; SmPC, summary of product characteristics.

1. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025;
2. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025.

Warnings and precautions (3/3)

Special warning and precautions for use

Patients with advanced or unresectable HCC with any of the following were excluded from clinical studies:*[1]

- Child–Pugh Score B or C
- Main portal vein thrombosis
- Liver transplant
- Uncontrolled hypertension
- History of, or current brain metastases
- Spinal cord compression
- Co-infection of viral hepatitis B and hepatitis C
- Active or prior documented gastrointestinal bleeding within 12 months
- Ascites requiring non-pharmacologic intervention within 6 months
- Hepatic encephalopathy within 12 months before the start of treatment
- Active or prior documented autoimmune or inflammatory disorders

In the absence of data, **IMFINZI and IMJUDO should be used with caution in these populations** after careful consideration of the potential benefit/risk on an individual basis*[1]

Please refer to the individual SmPCs for the complete safety profiles of IMFINZI and IMJUDO[1,2]

Please see section 4.4 of the individual SmPCs for further information on the special warning and precautions for use of IMFINZI and IMJUDO[1,2]

*This comprehensive list is specific to patients with advanced or unresectable HCC as per the SmPC for IMJUDO.
HCC, hepatocellular carcinoma; SmPC, summary of product characteristics.

1. IMJUDO. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/14841/smpc. Accessed December 2025;
2. IMFINZI. Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/9495/smpc. Accessed December 2025.

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