VYLOY™ Dosing and AE Management Guide

Indication

VYLOY™ (zolbetuximab) in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction (GEJ) adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.[1]

Selected Safety Information

Warnings and Precautions

Hypersensitivity reactions in patients treated with VYLOY in combination with fluoropyrimidine and platinum-containing chemotherapy during clinical studies were characterized by anaphylactic reaction or drug hypersensitivity. Monitor patients during and after infusion with VYLOY (at least 2 hours, or longer if clinically indicated) for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (e.g., urticaria, repetitive cough, wheeze and throat tightness/change in voice). If an anaphylactic reaction occurs, administration of VYLOY should be immediately and permanently discontinued and appropriate medical therapy administered. For any Grade 3 or 4 hypersensitivity reaction or hypersensitivity reaction with features of anaphylaxis, administration of VYLOY should be immediately and permanently discontinued and appropriate medical therapy instituted based on the type of reaction. For any Grade 2 hypersensitivity reaction, interrupt the VYLOY infusion until Grade ≤1, then resume the infusion at a reduced infusion rate for the remaining infusion. Pre-medicate the patient with antihistamines for the next infusion, administer per the infusion rates in the VYLOY Singapore Approved Package Insert, and closely monitor the patient for symptoms and signs of a hypersensitivity reaction. The infusion rate may be gradually increased as tolerated.

Please see Important Safety Information on pages 19-20.

VYLOY™

zolbetuximab

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Focusing on helping you support patients

Use this guide to learn about administering VYLOY to your patients and how to support them throughout treatment.

In the following pages, you'll find out about:

Dosing and administration of VYLOY

Understanding possible adverse events

Helping patients understand their infusion treatment

Treating nausea and vomiting

Please see Important Safety Information on pages 19-20.

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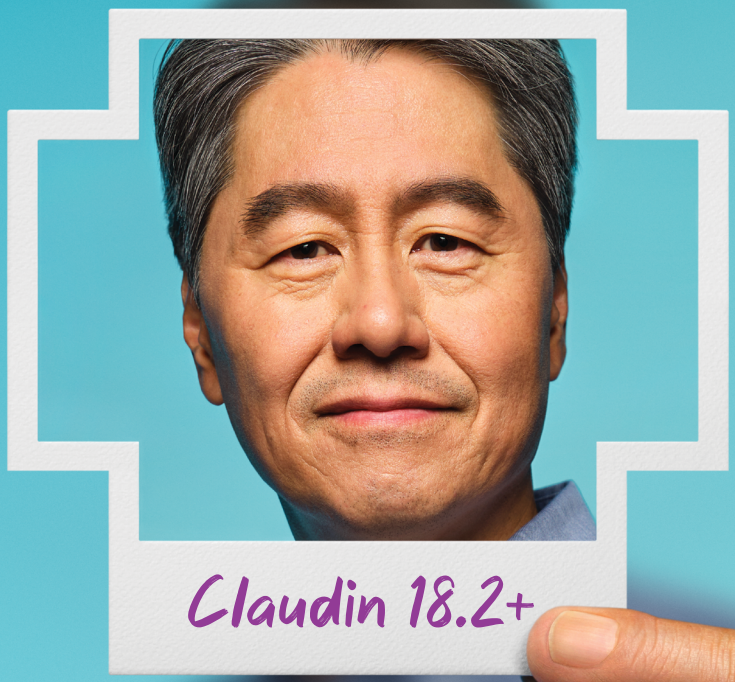

Selected Safety Information

Warnings and Precautions

Infusion-related reaction (IRR) has occurred during clinical studies with VYLOY in combination with fluoropyrimidine and platinum-containing chemotherapy. Monitor patients for signs and symptoms of infusion-related reaction including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. These signs and symptoms are usually reversible with the interruption of the infusion. For Grade 3 or 4 IRRs, administration of VYLOY should be immediately and permanently discontinued and appropriate medical therapy instituted. For Grade 2 IRRs, interrupt the VYLOY infusion until Grade ≤1, then resume the infusion at a reduced infusion rate for the remaining infusion. Pre-medicate the patient with antihistamines for the next infusion, administer per the infusion rates in the VYLOY Singapore Approved Package Insert, and closely monitor the patient for symptoms and signs of an IRR. The infusion rate may be gradually increased as tolerated.

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VYLOY is a first-in-class Claudin 18.2-directed monoclonal antibody for advanced* gastric/ GEJ adenocarcinoma[2-3]

Based on two global phase 3 clinical trials, it is estimated that:

38% **OF PATIENTS** with advanced* G/GEJ adenocarcinoma are CLDN18.2+ and may be candidates for VYLOY + chemotherapy[2-3†‡]

Data from 2 global randomised Phase 3 studies: SPOTLIGHT, which included 2,403 assessable patients, of which 922 were CLDN18.2 positive; and GLOW, which included 2,104 assessable patients, of which 808 were CLDN18.2 positive.[2,3]

VYLOY was studied in combination with mFOLFOX6 or CAPOX in two Phase 3 clinical trials[1]

Both trials (SPOTLIGHT and GLOW) included progression-free survival (primary endpoint) and overall survival (key secondary endpoint) in evaluating VYLOY + chemotherapy‡ vs chemotherapy alone.[1]

*Locally advanced unresectable or metastatic.

†Claudin 18.2 positive (CLDN18.2+) is defined as ≥75% of tumour cells demonstrating moderate to strong membranous CLDN18 staining by IHC.[2,3]

‡Fluoropyrimidine- and platinum-containing chemotherapy.

CLDN18.2=Claudin 18.2; **GEJ**=gastric/gastro-oesophageal junction.

LEARN MORE ABOUT VYLOY AND EXPLORE RESULTS FROM TWO PHASE 3 CLINICAL TRIALS (SPOTLIGHT AND GLOW) AT VYLOY.COM.SG

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02 Dosing and Administration

VYLOY infusion

VYLOY can be administered every 2 or 3 weeks aligning with selected chemotherapy dosing schedule[1]

BEFORE THE FIRST INFUSION[1]
Symptoms of nausea and/or vomiting should be resolved to Grade ≤1

PRETREATMENT[1]
Prior to each infusion, pretreat patients with a combination of antiemetics (e.g., NK-1 receptor blockers and/or 5-HT3 receptor blockers, as well as other drugs as indicated) for the prevention of nausea and vomiting

Recommended dosage and infusion rates[1]

VYLOY Dose*		*Initial* Infusion Rate (first 30-60 minutes)	*Subsequent* Infusion Rate
Single Loading Dose (Cycle 1, Day 1)	800 mg/m²	100 mg/m²/hr	200-400 mg/m²/hr
Maintenance Doses	600 mg/m² every 3 weeks or 400 mg/m² every 2 weeks	75 mg/m²/hr or 50 mg/m²/hr	150-300 mg/m²/hr or 100-200 mg/m²/hr

Refer to the fluoropyrimidine- or platinum-containing chemotherapy Singapore Approved Package Insert regarding the dosing information for chemotherapy.

- In the absence of adverse reactions after 30-60 minutes, the infusion rate can be increased to the subsequent infusion rate as tolerated[1]
- If VYLOY and chemotherapy† are administered on the same day, VYLOY must be administered first[1]

*Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy.[1]
† Fluoropyrimidine- and platinum-containing chemotherapy.[1]

As shown above: The infusions are started at a slower rate for the first 30-60 minutes to help mitigate potential adverse events. The rate can be increased for the remainder of the infusion as tolerated.

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VYLOY administration

Infusion timing

Prior to each infusion of VYLOY, premedicate patients with antiemetics.[1]

2hr+

Immediately administer the infusion over a minimum of 2 hours through an intravenous line. Do not administer as an IV push or bolus.[1]

If the infusion time exceeds the recommended storage time at room temperature (6 hours from end of preparation of infusion solution), the infusion bag must be discarded and a new infusion bag prepared to continue the infusion.

Infusion line considerations[1]

- In-line filters (pore size of 0.2 micron with materials listed in the Singapore Approved Package Insert) are recommended to be used during administration
- Do not coadminister other drugs through the same infusion line
- **No incompatibilities** have been observed with closed system transfer device or central port composed of certain materials (see VYLOY Singapore Approved Package Insert for more details)

Selected Safety Information

During clinical studies, **nausea and vomiting** were the most frequently observed gastrointestinal (GI) adverse reactions with VYLOY in combination with fluoropyrimidine and platinum-containing chemotherapy treatment. Nausea and vomiting occurred more often during the first cycle of treatment but decreased in incidence with subsequent cycles of treatment. To prevent nausea and vomiting, pretreatment with a combination of antiemetics is recommended prior to each infusion of VYLOY. During and after infusion, patients should be monitored and managed using standard of care, including antiemetics or fluid replacement, as clinically indicated. For Grade 4 vomiting, permanently discontinue treatment with VYLOY. For Grade 2 or 3 nausea or vomiting, interrupt the VYLOY infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion. For the next infusion, administer per the infusion rates in the VYLOY Singapore Approved Package Insert and closely monitor the patient for symptoms and signs of nausea or vomiting. The infusion rate may be gradually increased as tolerated.

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VYLOY adverse event management[1]

No dose reduction for VYLOY is recommended. Adverse events for VYLOY are managed by reducing the infusion rate, interrupting (pausing) infusion, withholding the dose, and/or discontinuing treatment as outlined in the table below.

Adverse Reaction	Severity	Dose Modification
Hypersensitivity reactions	Anaphylactic reactions, suspected anaphylaxis, Grade 3 or 4	Immediately stop the infusion and permanently discontinue.
	Grade 2	• Pause the infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion • For the next infusion, premedicate and administer per the infusion rates in Table 3 in the VYLOY Singapore Approved Package Insert
Infusion related reactions	Grade 3 or 4	Immediately stop the infusion and permanently discontinue.
	Grade 2	• Pause the infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion • For the next infusion, premedicate and administer per the infusion rates in Table 3 in the VYLOY Singapore Approved Package Insert
Nausea	Grade 2 or 3	• Pause the infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion • For the next infusion, premedicate and administer per the infusion rates in Table 3 in the VYLOY Singapore Approved Package Insert
Vomiting	Grade 4	Permanently discontinue.
	Grade 2 or 3	• Pause the infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion • For the next infusion, premedicate and administer per the infusion rates in Table 3 in the VYLOY Singapore Approved Package Insert

- Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.03 (NCICTCAE v4.03) where Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, Grade 4 is life-threatening[2,3]

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03 Adverse Events Treatment

Adverse events in clinical trials

Recognising the possible adverse events[1]

In the clinical trials, the most common adverse reactions with VYLOY were nausea, vomiting, decreased appetite, neutropenia, neutrophil count decreased, weight decreased, pyrexia, hypoalbuminaemia, oedema peripheral, hypertension, dyspepsia, chills, salivary hypersecretion, infusion related reaction, and drug hypersensitivity.

SPOTLIGHT Trial: Adverse Events[2]

TREATMENT-EMERGENT ADVERSE EVENTS (TEAEs)[2]	VYLOY + mFOLFOX6 (n=279)		PLACEBO + mFOLFOX6 (n=278)	
	ANY GRADE, n (%)	GRADE ≥3, n (%)	ANY GRADE, n (%)	GRADE ≥3, n (%)
Any adverse event	278 (>99)	242 (87)	277 (>99)	216 (78)
Nausea	230 (82)	45 (16)	169 (61)	18 (6)
Vomiting	188 (67)	45 (16)	99 (36)	16 (6)
Decreased appetite	131 (47)	16 (6)	93 (33)	9 (3)
Diarrhoea	110 (39)	12 (4)	122 (44)	9 (3)
Peripheral sensory neuropathy	106 (38)	11 (4)	118 (42)	15 (5)
Neutropaenia	102 (37)	79 (28)	94 (34)	65 (23)
Anaemia	100 (36)	24 (9)	104 (37)	29 (9)
Constipation	99 (35)	3 (1)	112 (40)	2 (1)
Neutrophil count decreased	95 (34)	69 (25)	91 (33)	69 (25)
Fatigue	78 (28)	17 (6)	91 (33)	14 (5)
Asthenia	74 (27)	20 (7)	64 (23)	7 (3)
Abdominal pain	67 (24)	12 (4)	82 (29)	6 (2)
Stomatitis	58 (21)	7 (3)	57 (21)	3 (1)
Weight decreased	55 (20)	5 (2)	54 (19)	2 (1)
Pyrexia	54 (19)	1 (<1)	48 (17)	1 (<1)
White blood cell count decreased	50 (18)	8 (3)	46 (17)	16 (6)
Hypokalaemia	50 (18)	16 (6)	41 (15)	10 (4)
Oedema peripheral	49 (18)	2 (1)	26 (9)	0
Aspartate aminotransferase increased	49 (18)	4 (1)	44 (16)	7 (3)
Abdominal pain upper	47 (17)	4 (1)	32 (12)	0
Paraesthesia	44 (16)	6 (2)	46 (17)	4 (1)
Hypoalbuminaemia	43 (15)	11 (4)	17 (6)	2 (1)
Dysgeusia	41 (15)	1 (<1)	40 (14)	0
Platelet count decreased	40 (14)	3 (1)	49 (18)	6 (2)
Alanine aminotransferase increased	34 (12)	2 (1)	47 (17)	7 (3)
Thrombocytopaenia	28 (10)	4 (1)	45 (16)	4 (1)

- Median duration of exposure to VYLOY in combination with mFOLFOX6 was 6.2 months[2]

See page 9 for details on infusion rate adjustments for adverse reaction treatment.

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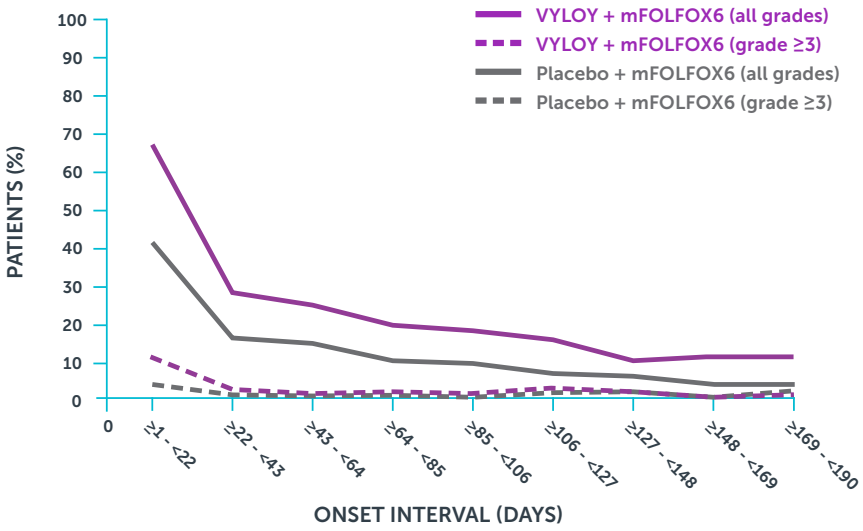
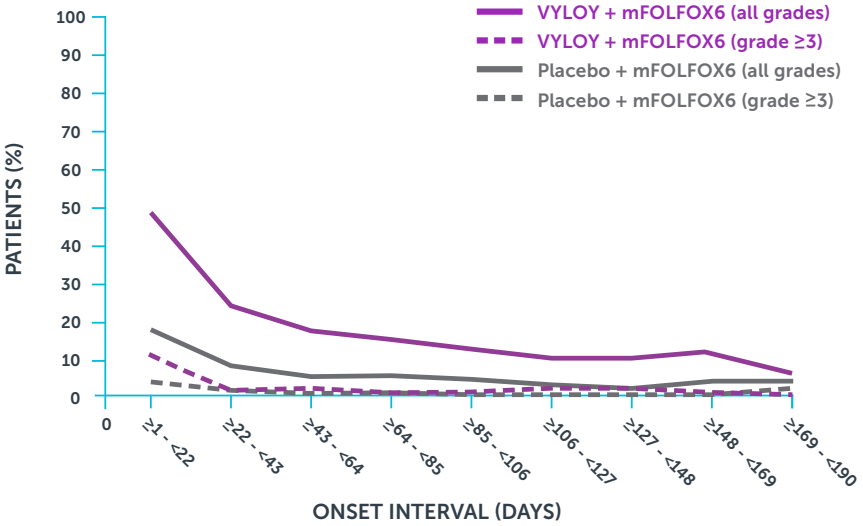
In the SPOTLIGHT clinical study, nausea and vomiting[2]:

- Were the most common AEs when VYLOY was given with mFOLFOX6 (majority were grades 1 & 2)
- Were managed by infusion rate modifications, infusion interruptions, and the use of antiemetics
- Occurred more often in the first cycle but decreased in incidence with subsequent cycles
- Have been confirmed as important identified risks. Adverse events, graded according to NCI CTCAE v4.03, were monitored throughout the trial and for 90 days after treatment discontinuation. Adverse event preferred terms were defined according to the Medical Dictionary for Regulatory Activities terminology version 25.0. Grade 4 nausea is not defined in Common Terminology Criteria for Adverse Events v4.03 and was determined and managed at investigator discretion. These data are not generalisable and cannot be used to predict adverse event outcomes. These data are from a Phase 3 global randomised multicentre trial. The results presented are provided only as descriptive clinical information.

Nausea: All occurrences in SPOTLIGHT[4]



Vomiting: All occurrences in SPOTLIGHT[4]



GLOW Trial: Adverse Events[3]

Adverse events reported in ≥15% (any grade)[3]*

TREATMENT-EMERGENT ADVERSE EVENTS[3]	VYLOY + CAPOX (n=254)		PLACEBO + CAPOX (n=249)	
	ANY GRADE, n (%)	GRADE ≥3, n (%)	ANY GRADE, n (%)	GRADE ≥3, n (%)
Any adverse event	251 (98.8)	185 (72.8)	244 (98.0)	174 (69.9)
Nausea	174 (68.5)	22 (8.7)	125 (50.2)	6 (2.4)
Vomiting	168 (66.1)	31 (12.2)	77 (30.9)	9 (3.6)
Decreased appetite	105 (41.3)	17 (6.7)	84 (33.7)	4 (1.6)
Anaemia	90 (35.4)	27 (10.6)	91 (36.5)	28 (11.2)
Diarrhoea	80 (31.5)	15 (5.9)	86 (34.5)	18 (7.2)
Neutrophil count decreased	70 (27.6)	26 (10.2)	59 (23.7)	24 (9.6)
Aspartate aminotransferase increased	63 (24.8)	6 (2.4)	72 (28.9)	7 (2.8)
Platelet count decreased	61 (24.0)	19 (7.5)	60 (24.1)	20 (8.0)
Hypoalbuminaemia	57 (22.4)	8 (3.1)	35 (14.1)	4 (1.6)
Peripheral sensory neuropathy	56 (22.0)	1 (0.4)	56 (22.5)	6 (2.4)
White blood cell count decreased	51 (20.1)	5 (2.0)	39 (15.7)	9 (3.6)
Neutropaenia	50 (19.7)	18 (7.1)	35 (14.1)	7 (2.8)
Weight decreased	50 (19.7)	1 (0.4)	25 (10.0)	1 (0.4)
Alanine aminotransferase increased	48 (18.9)	2 (0.8)	52 (20.9)	7 (2.8)
Palmar-plantar erythrodysesthesia	41 (16.1)	4 (1.6)	49 (19.7)	9 (3.6)
Abdominal pain	40 (15.7)	1 (0.4)	54 (21.7)	4 (1.6)
Constipation	39 (15.4)	–	52 (20.9)	–
Fatigue	34 (13.4)	7 (2.8)	42 (16.9)	9 (3.6)

- Median duration of exposure to VYLOY was 6.4 months[3]

See page 9 for details on infusion rate adjustments for adverse reaction treatment.

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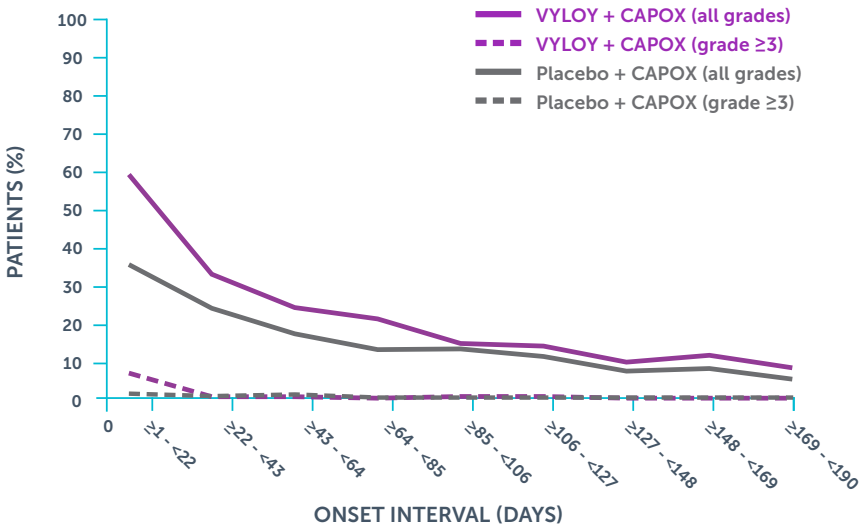
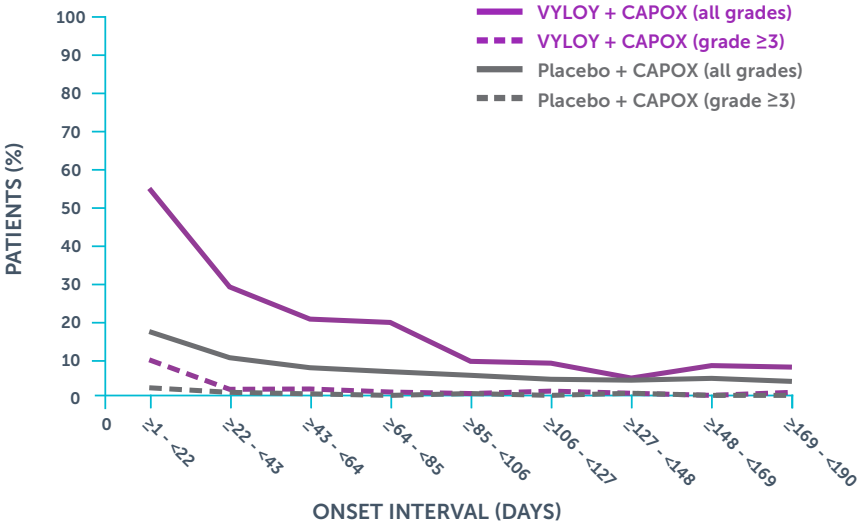
In the GLOW clinical study, nausea and vomiting[3]:

- Were the most common AEs when VYLOY was given with CAPOX (majority were grades 1 & 2)
- Were managed by infusion rate modifications, infusion interruptions, and the use of antiemetics
- Occurred more often in the first cycle but decreased in incidence with subsequent cycles
- Have been confirmed as important identified risks. Adverse events, graded according to NCI CTCAE v4.03, were monitored throughout the trial and for 90 days after treatment discontinuation. Adverse event preferred terms were defined according to the Medical Dictionary for Regulatory Activities terminology version 25.0. Grade 4 nausea is not defined in Common Terminology Criteria for Adverse Events v4.03 and was determined and managed at investigator discretion. These data are not generalisable and cannot be used to predict adverse event outcomes. These data are from a Phase 3 global randomised multicentre trial. The results presented are provided only as descriptive clinical information.

Nausea: All occurrences in GLOW[3]



Vomiting: All occurrences in GLOW[3]



Treating nausea and vomiting

If a patient is experiencing nausea and/or vomiting prior to administration of VYLOY, the symptoms should be resolved to Grade ≤1 before administering the first infusion.

During/after infusion

Monitor and manage using standard of care (includes antiemetics or fluid replacement as clinically indicated).[1]

Other advice on antiemetics

REMIND DOCTORS TO PRESCRIBE
antiemetics so that they are readily available (during infusion and at home)

REMIND PATIENTS TO TAKE
antiemetics on time as prescribed

REMIND PATIENTS TO REFILL
their antiemetic prescriptions

TIP: Remind patients to tell their healthcare provider about all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VYLOY with certain other medicines may cause side effects.

This information is for informational purposes only and is not meant to replace the advice of a healthcare professional.

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04 Storage and Handling

Storage times for a prepared infusion bag[1]

The following times include the administration period

Stored under refrigeration at 2°C to 8°C for no longer than 24 hours from the end of the preparation of the infusion bag. Do not freeze.

Stored at room temperature (not more than 30°C) for no longer than 12 hours from when the prepared infusion bag is removed from the refrigerator. Do not expose to direct sunlight.

Discard unused prepared infusion bags beyond the recommended storage time.

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05 Important Safety Information

Important Safety Information

Warnings and Precautions

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Infusion-related reaction (IRR) has occurred during clinical studies with Vyloy in combination with fluoropyrimidine and platinum-containing chemotherapy. Monitor patients for signs and symptoms of infusion-related reaction including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. These signs and symptoms are usually reversible with the interruption of the infusion. For Grade 3 or 4 IRRs, administration of Vyloy should be immediately and permanently discontinued and appropriate medical therapy instituted. For Grade 2 IRRs, interrupt the Vyloy infusion until Grade ≤1, then resume the infusion at a reduced infusion rate for the remaining infusion. Pre-medicate the patient with antihistamines for the next infusion, administer per the infusion rates in the VYLOY Singapore Approved Package Insert, and closely monitor the patient for symptoms and signs of an IRR. The infusion rate may be gradually increased as tolerated.

During clinical studies, **nausea and vomiting** were the most frequently

Please see Important Safety Information continued on page 20.

Important Safety Information, continued

observed gastrointestinal (GI) adverse reactions with VYLOY in combination with fluoropyrimidine and platinum-containing chemotherapy treatment. Nausea and vomiting occurred more often during the first cycle of treatment but decreased in incidence with subsequent cycles of treatment. To prevent nausea and vomiting, pretreatment with a combination of antiemetics is recommended prior to each infusion of VYLOY. During and after infusion, patients should be monitored and managed using standard of care, including antiemetics or fluid replacement, as clinically indicated. For Grade 4 vomiting, permanently discontinue treatment with VYLOY. For Grade 2 or 3 nausea or vomiting, interrupt the VYLOY infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion. For the next infusion, administer per the infusion rates in Table 3, and closely monitor the patient for symptoms and signs of nausea or vomiting. The infusion rate may be gradually increased as tolerated.

Specific Populations

Lactation - Advise a lactating woman not to breastfeed during treatment with VYLOY.

References:

1. VYLOY Singapore Approved Package Insert. **2.** Shitara K, Lordick F, Bang YJ, et al. Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. Lancet (Epub ahead of print) 04-14-2023. **3.** Shah MA, Shitara K, Ajani JA, et al. Zolbetuximab plus CAPOX in CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma: the randomized, phase 3 GLOW trial. Nat Med (Epub) 07-31-2023. **4.** Supplement to: Shitara K, Lordick F, Bang YJ, et al. Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. Lancet (Epub ahead of print) 04-14-2023.

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To learn more, visit:

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Photos used in this document include models, not actual patients.

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Report any adverse events to Astellas Pharma Singapore Pte. Ltd. at pv@sg.astellas.com.
Alternatively, adverse events may be reported to the Health Sciences Authority at
Tel: 6866 1111, or online at https://www.hsa.gov.sg/adverse-events

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