VYLOY® Infusion and Treatment Management Guide

INDICATION

VYLOY® (zolbetuximab-clzb), in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test.

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions, including serious anaphylaxis reactions, and serious and fatal infusion-related reactions (IRR) have been reported in clinical studies when VYLOY has been administered. **Any grade hypersensitivity reactions,** including anaphylactic reactions, occurring with VYLOY in combination with mFOLFOX6 or CAPOX was 18%. **Severe (Grade 3 or 4) hypersensitivity reactions,** including anaphylactic reactions, occurred in 2% of patients. Seven patients (1.3%) permanently discontinued VYLOY for hypersensitivity reactions, including two patients (0.4%) who permanently discontinued VYLOY due to anaphylactic reactions. Seventeen (3.2%) patients required dose interruption, and three patients (0.6%) required infusion rate reduction due to hypersensitivity reactions. **All grade IRRs** occurred in 3.2% in patients administered VYLOY in combination with mFOLFOX6 or CAPOX. Severe (Grade 3) IRRs occurred in 2 (0.4%) patients who received VYLOY. An IRR led to permanent discontinuation of VYLOY in 2 (0.4%) patients and dose interruption in 7 (1.3%) patients. The infusion rate was reduced for VYLOY for 2 (0.4%) patients due to an IRR. Monitor patients during infusion with VYLOY and for 2 hours after completion of infusion or longer if clinically indicated, for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (urticaria, repetitive cough, wheeze and throat tightness/change in voice). Monitor patients for signs and symptoms of IRRs including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. If a severe or life-threatening hypersensitivity or IRR reaction occurs, discontinue VYLOY permanently, treat symptoms according to standard medical care, and monitor until symptoms resolve. For any Grade 2 hypersensitivity or IRR, interrupt the VYLOY infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion. Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting. Premedicate the patient with antihistamines for the subsequent infusions, 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, and accompanying full Prescribing Information.

VYLOY®
zolbetuximab-clzb
for injection 100mg vial

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 reactions

Helping patients understand their infusion treatment

Treating nausea and vomiting

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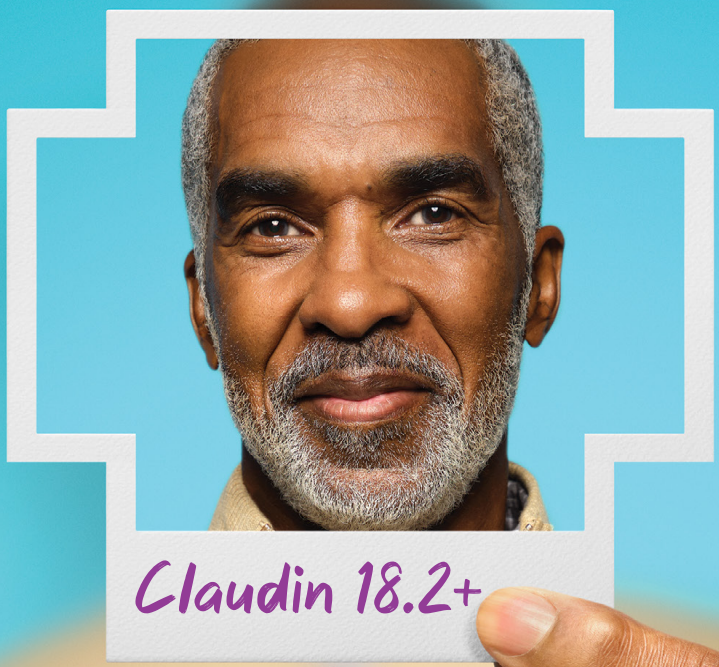

SELECT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Severe Nausea and Vomiting. VYLOY is emetogenic. Nausea and vomiting occurred more often during the first cycle of treatment. **All grade nausea and vomiting** occurred in 82% and 67% respectively of patients treated with VYLOY in combination with mFOLFOX6 and 69% and 66% in combination with CAPOX, respectively. **Severe (Grade 3) nausea** occurred in 16% and 9% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX respectively. **Severe (Grade 3) vomiting** occurred in 16% and 12% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX. Nausea led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 18 (3.4%) patients and dose interruption in 147 (28%) patients. Vomiting led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 20 (3.8%) patients and dose interruption in 150 (28%) patients. Pretreat with antiemetics prior to each infusion of VYLOY. Manage patients during and after infusion with antiemetics or fluid replacement. Interrupt the infusion, or permanently discontinue VYLOY based on severity.

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VYLOY is a first-in-class FDA-approved monoclonal antibody that targets a novel biomarker in advanced* G/GEJ cancer: claudin 18.2[1-3]

According to estimates from two global Phase 3 studies:

38% **OF PATIENTS with advanced* G/GEJ adenocarcinoma are CLDN18.2+ and may be candidates for VYLOY + chemo[1-3†‡]**

Data from 2 global randomized 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]

PFS + OS

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

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

*Locally advanced unresectable or metastatic.[1]

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

‡Fluoropyrimidine- and platinum-containing chemotherapy.[1]

CLDN18.2=claudin 18.2; **G/GEJ**=gastric/gastroesophageal junction.

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

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02 Dosing and Administration

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VYLOY infusion

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

PRIOR TO ADMINISTRATION[1]

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

PREMEDICATION[1]

Prior to each VYLOY infusion, premedicate 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.

VYLOY Dosing[1*]

First dose:
800 mg/m^2 intravenously

Subsequent doses:
600 mg/m^2 intravenously every **3 weeks**
or
400 mg/m^2 intravenously every **2 weeks**

VYLOY Administration[1]

If VYLOY + chemotherapy[†] are administered on the same day, VYLOY must be administered first.

RECOMMENDED DURATION OF TREATMENT IS UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY[1]

*Administer VYLOY in combination with fluoropyrimidine- and platinum-containing chemotherapy.[1]
[†] Fluoropyrimidine- and platinum-containing chemotherapy.[1]
5-HT3=5-hydroxytryptamine; **NK-1**=neurokinin-1.

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Recommended VYLOY dosage and infusion rates[1]

VYLOY Dose		Initial Infusion Rate (first 30-60 minutes)	Subsequent Infusion Rate
First Dose	800 mg/m²	100 mg/m²/hr	200-265 mg/m²/hr
Subsequent Doses	600 mg/m² every 3 weeks	75 mg/m²/hr	150-265 mg/m²/hr
	or	or	or
	400 mg/m² every 2 weeks	50 mg/m²/hr	100-200 mg/m²/hr

first dose

For the first VYLOY dose, the estimated minimum infusion time is approximately 3.5 hours. Total infusion time will depend on dose interruptions or infusion rate reductions.[1]

subsequent doses

For subsequent VYLOY doses, the estimated minimum infusion time is approximately 2.5 hours. Total infusion time will depend on dose interruptions or infusion rate reductions.[1]

- 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]

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

*Fluoropyrimidine- and platinum-containing chemotherapy.[1]

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ADVERSE REACTIONS

Most common adverse reactions (≥15%): Nausea, vomiting, fatigue, decreased appetite, diarrhea, peripheral sensory neuropathy, abdominal pain, constipation, decreased weight, hypersensitivity reactions, and pyrexia.

Most common laboratory abnormalities (≥15%): Decreased neutrophil count, decreased leucocyte count, decreased albumin, increased creatinine, decreased hemoglobin, increased glucose, decreased lymphocyte count, increased aspartate aminotransferase, decreased platelets, increased alkaline phosphatase, increased alanine aminotransferase, decreased glucose, decreased sodium, increased phosphate, decreased potassium, and decreased magnesium.

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VYLOY administration

Infusion timing

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

Immediately administer the infusion through an intravenous line. Do not administer as an IV push or bolus.[1]

If the infusion time exceeds the recommended storage time (6 hours from end of preparation of infusion solution at room temperature or 16 hours from end of preparation of infusion solution under refrigeration), 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 Prescribing Information) are recommended to be used during administration
- Do not co-administer other drugs through the same infusion line
- **No incompatibilities** have been observed with closed system transfer devices or central ports composed of certain materials (see Prescribing Information for more details)

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ADVERSE REACTIONS

SPOTLIGHT Study: 279 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with mFOLFOX6

Serious adverse reactions occurred in 45% of patients treated with VYLOY in combination with mFOLFOX6; the **most common serious adverse reactions** (≥2%) were vomiting (8%), nausea (7%), neutropenia (2.9%), febrile neutropenia (2.9%), diarrhea (2.9%), intestinal obstruction (3.2%), pyrexia (2.5%), pneumonia (2.5%), respiratory failure (2.2%), pulmonary embolism (2.2%), decreased appetite (2.1%) and sepsis (2.0%). **Fatal adverse reactions** occurred in 5% of patients who received VYLOY in combination with mFOLFOX6 including sepsis (1.4%), pneumonia (1.1%), respiratory failure (1.1%), intestinal obstruction (0.7%), acute hepatic failure (0.4%), acute myocardial infarction (0.4%), death (0.4%), disseminated intravascular coagulation (0.4%), encephalopathy (0.4%), and upper gastrointestinal hemorrhage (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 20% of patients; the **most common adverse reactions leading to discontinuation** (≥2%) were nausea and vomiting. Dosage interruptions of VYLOY due to an adverse reaction occurred in 75% of patients; the **most common adverse reactions leading to dose interruption** (≥5%) were nausea, vomiting, neutropenia, abdominal pain, fatigue, and hypertension.

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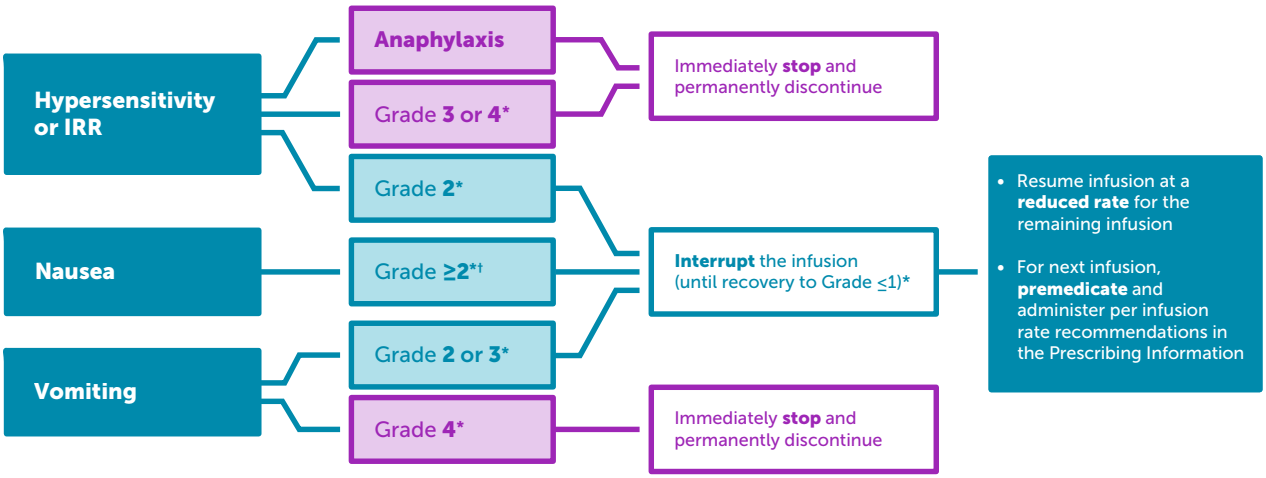
VYLOY adverse reaction management[1]

No dose reduction for VYLOY is recommended. Adverse reactions for VYLOY are managed by reducing the infusion rate, interruption of the infusion, withholding the dose, and/or permanently discontinuing VYLOY as described in the table below.

INFUSION MODIFICATIONS FOR VYLOY-RELATED ADVERSE REACTIONS MANAGEMENT, INCLUDING NAUSEA AND VOMITING



Grade 1: mild;
Grade 2: moderate;
Grade 3: severe or medically significant but not immediately life-threatening;
Grade 4: life-threatening consequences.[4*]

*Toxicity was graded per NCI CTCAE v5.0. Per NCI CTCAE v5.0, grade refers to the severity of the adverse reactions.
†NCI CTCAE v5.0 does not list Grade 4 nausea.

IRR=independent review committee; **NCI CTCAE=**National Cancer Institute Common Terminology Criteria for Adverse Events.

SELECT SAFETY INFORMATION

ADVERSE REACTIONS

GLOW Study: 254 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with CAPOX

Serious adverse reactions occurred in 47% of patients treated with VYLOY in combination with CAPOX; the **most common serious adverse reactions** (≥2%) were vomiting (6%), nausea (4.3%), decreased appetite (3.9%), decreased platelet count (3.1%), upper gastrointestinal hemorrhage (2.8%), diarrhea (2.8%), pneumonia (2.4%), pulmonary embolism (2.3%), and pyrexia (2.0%). **Fatal adverse reactions** occurred in 8% of patients who received VYLOY in combination with CAPOX including sepsis (1.2%), pneumonia (0.4%), death (0.8%), upper gastrointestinal hemorrhage (0.8%), cerebral hemorrhage (0.8%), abdominal infection (0.4%), acute respiratory distress syndrome (0.4%), cardio-respiratory arrest (0.4%), decreased platelet count (0.4%), disseminated intravascular coagulation (0.4%), dyspnea (0.4%), gastric perforation (0.4%), hemorrhagic ascites (0.4%), procedural complication (0.4%), sudden death (0.4%), and syncope (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 19% of patients; the **most common adverse reaction leading to discontinuation** (≥2%) was vomiting. Dosage interruption of VYLOY due to an adverse reaction occurred in 55% of patients; the **most common adverse reactions leading to dose interruption** (≥2%) were nausea, vomiting, neutropenia, thrombocytopenia, anemia, fatigue, infusion-related reaction, and abdominal pain.

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03 Adverse Reaction (AR) Treatment

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Adverse reactions in clinical trials

Recognizing the possible adverse reactions[1]

SPOTLIGHT Trial: Adverse reactions reported in ≥15% of patients treated with VYLOY with a difference between arms of ≥5% compared to placebo[1]

ADVERSE REACTION		VYLOY with mFOLFOX6 (n=279)		PLACEBO with mFOLFOX6 (n=278)	
		All Grades (%)	Grade 3-4 (%)	All Grades (%)	Grade 3-4 (%)
Gastrointestinal disorders	Nausea	82	16	61	7
	Vomiting	67	16	36	6
Metabolism and nutrition disorders	Decreased appetite	47	6	34	3.2
General disorders and administration site conditions	Peripheral edema	18	0.7	9	0

Median duration of exposure to VYLOY in combination with mFOLFOX6 was 6.2 months (range: 1 day to 40.9 months).

See page 11 for details on infusion rate adjustments for adverse reaction treatment.

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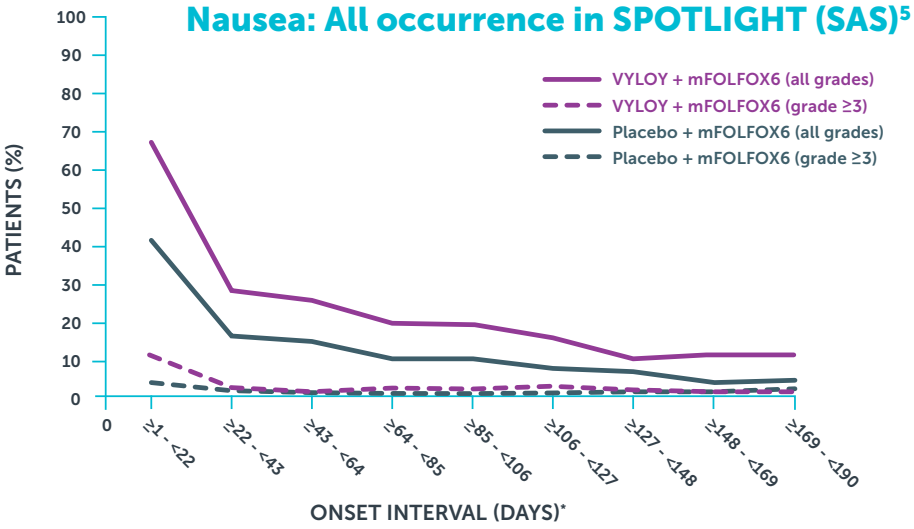
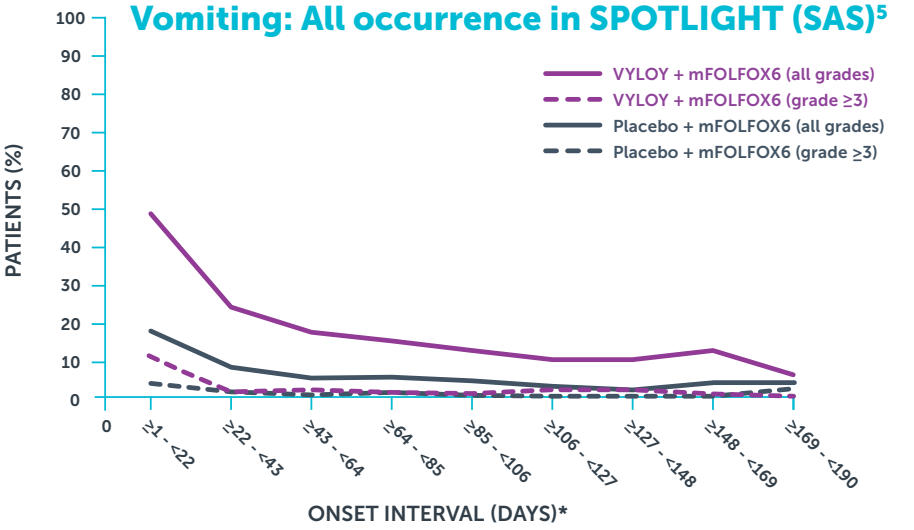
In the SPOTLIGHT clinical study, nausea and vomiting:

- Were the most common AEs when VYLOY was given with mFOLFOX6 (majority were grades 1 & 2)[1]
- Nausea and vomiting were managed by infusion rate guidelines, infusion interruptions, and the use of antiemetics[2]
- Occurred more often in the first cycle[1]
- Nausea and vomiting 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 generalizable and cannot be used to predict adverse event outcomes. These data are from the safety analysis set (SAS) in a Phase 3, global, randomized, multicenter trial (VYLOY + mFOLFOX6: n=279; Placebo + mFOLFOX6: n=278). The results presented are provided only as descriptive clinical information.





*The onset day in the onset interval was defined as the date of onset minus the date of first dose plus 1.

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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

Manage patients during and after infusion with antiemetics or fluid replacement. Interrupt the infusion, or permanently discontinue VYLOY based on severity (see Prescribing Information for more details).[1]

Other advice on antiemetics[1]

GET PRESCRIPTION APPROVAL
so that antiemetics 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.

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

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Storage times for a prepared infusion bag[1]

The following times include the administration period

Stored under refrigeration at 2°C to 8°C (36°F to 46°F) for no longer than 16 hours from the end of the preparation of the infusion bag. Do not freeze.

Stored at room temperature at 15°C to 30°C (59°F to 86°F) for no longer than 6 hours from the end of the infusion bag preparation to the completion of the infusion.

Discard prepared infusion bags beyond the recommended storage time.

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05 Important Safety Information

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions, including serious anaphylaxis reactions, and serious and fatal infusion-related reactions (IRR) have been reported in clinical studies when VYLOY has been administered. **Any grade hypersensitivity reactions,** including anaphylactic reactions, occurring with VYLOY in combination with mFOLFOX6 or CAPOX was 18%. **Severe (Grade 3 or 4) hypersensitivity reactions,** including anaphylactic reactions, occurred in 2% of patients. Seven patients (1.3%) permanently discontinued VYLOY for hypersensitivity reactions, including two patients (0.4%) who permanently discontinued VYLOY due to anaphylactic reactions. Seventeen (3.2%) patients required dose interruption, and three patients (0.6%) required infusion rate reduction due to hypersensitivity reactions. **All grade IRRs** occurred in 3.2% in patients administered VYLOY in combination with mFOLFOX6 or CAPOX. Severe (Grade 3) IRRs occurred in 2 (0.4%) patients who received VYLOY. An IRR led to permanent discontinuation of VYLOY in 2 (0.4%) patients and dose interruption in 7 (1.3%) patients. The infusion rate was reduced for VYLOY for 2 (0.4%) patients due to an IRR. Monitor patients during infusion with VYLOY and for 2 hours after completion of infusion or longer if clinically indicated, for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (urticaria, repetitive cough, wheeze and throat tightness/change in voice). Monitor patients for signs and symptoms of IRRs including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. If a severe or life-threatening hypersensitivity or IRR reaction occurs, discontinue VYLOY permanently, treat symptoms according to standard medical care, and monitor until symptoms resolve. For any Grade 2 hypersensitivity or IRR, interrupt the VYLOY infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion. Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting. Premedicate the patient with antihistamines for the subsequent infusions, and closely monitor the patient for symptoms and signs of a hypersensitivity reaction. The infusion rate may be gradually increased as tolerated.

Severe Nausea and Vomiting. VYLOY is emetogenic. Nausea and vomiting occurred more often during the first cycle of treatment. **All grade nausea and vomiting** occurred in 82% and 67% respectively of patients treated with VYLOY in combination with mFOLFOX6 and 69% and 66% in combination with CAPOX, respectively. **Severe (Grade 3) nausea** occurred in 16% and 9% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX respectively. **Severe (Grade 3) vomiting** occurred in 16% and 12% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX. Nausea led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 18 (3.4%) patients and dose interruption in 147 (28%) patients. Vomiting led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 20 (3.8%) patients and dose interruption in 150 (28%) patients. Pretreat with antiemetics prior to each infusion of VYLOY. Manage patients during and after infusion with antiemetics or fluid replacement. Interrupt the infusion, or permanently discontinue VYLOY based on severity.

ADVERSE REACTIONS

Most common adverse reactions (≥15%): Nausea, vomiting, fatigue, decreased appetite, diarrhea, peripheral sensory neuropathy, abdominal pain, constipation, decreased weight, hypersensitivity reactions, and pyrexia.

Most common laboratory abnormalities (≥15%): Decreased neutrophil count, decreased leucocyte count, decreased albumin, increased creatinine, decreased hemoglobin, increased glucose, decreased lymphocyte count, increased aspartate aminotransferase, decreased platelets, increased alkaline phosphatase, increased alanine aminotransferase, decreased glucose, decreased sodium, increased phosphate, decreased potassium, and decreased magnesium.

SPOTLIGHT Study: 279 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with mFOLFOX6

Serious adverse reactions occurred in 45% of patients treated with VYLOY in combination with mFOLFOX6; the **most common serious adverse reactions** (≥2%) were vomiting (8%), nausea (7%), neutropenia (2.9%), febrile neutropenia (2.9%), diarrhea (2.9%), intestinal obstruction (3.2%), pyrexia (2.5%), pneumonia (2.5%),

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respiratory failure (2.2%), pulmonary embolism (2.2%), decreased appetite (2.1%) and sepsis (2.0%). **Fatal adverse reactions** occurred in 5% of patients who received VYLOY in combination with mFOLFOX6 including sepsis (1.4%), pneumonia (1.1%), respiratory failure (1.1%), intestinal obstruction (0.7%), acute hepatic failure (0.4%), acute myocardial infarction (0.4%), death (0.4%), disseminated intravascular coagulation (0.4%), encephalopathy (0.4%), and upper gastrointestinal hemorrhage (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 20% of patients; the **most common adverse reactions leading to discontinuation** (≥2%) were nausea and vomiting. Dosage interruptions of VYLOY due to an adverse reaction occurred in 75% of patients; the **most common adverse reactions leading to dose interruption** (≥5%) were nausea, vomiting, neutropenia, abdominal pain, fatigue, and hypertension.

GLOW Study: 254 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with CAPOX

Serious adverse reactions occurred in 47% of patients treated with VYLOY in combination with CAPOX; the **most common serious adverse reactions** (≥2%) were vomiting (6%), nausea (4.3%), decreased appetite (3.9%), decreased platelet count (3.1%), upper gastrointestinal hemorrhage (2.8%), diarrhea (2.8%), pneumonia (2.4%), pulmonary embolism (2.3%), and pyrexia (2.0%). **Fatal adverse reactions** occurred in 8% of patients who received VYLOY in combination with CAPOX including sepsis (1.2%), pneumonia (0.4%), death (0.8%), upper gastrointestinal hemorrhage (0.8%), cerebral hemorrhage (0.8%), abdominal infection (0.4%), acute respiratory distress syndrome (0.4%), cardio-respiratory arrest (0.4%), decreased platelet count (0.4%), disseminated intravascular coagulation (0.4%), dyspnea (0.4%), gastric perforation (0.4%), hemorrhagic ascites (0.4%), procedural complication (0.4%), sudden death (0.4%), and syncope (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 19% of patients; the **most common adverse reaction leading to discontinuation** (≥2%) was vomiting. Dosage interruption of VYLOY due to an adverse reaction occurred in 55% of patients; the **most common adverse reactions leading to dose interruption** (≥2%) were nausea, vomiting, neutropenia, thrombocytopenia, anemia, fatigue, infusion-related reaction, and abdominal pain.

SPECIFIC POPULATIONS

Lactation Advise lactating women not to breastfeed during treatment with VYLOY and for 8 months after the last dose.

References:

1. VYLOY [package insert]. Northbrook, IL: Astellas Pharma US, Inc. **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 2023;401(10389): 1655-1668. Errata in: Lancet 2023;402(10398):290; Lancet 2024;403(10421):30. **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 2023;29(8):2133-2141. **4**. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7. pdf. Accessed May 22, 2024. **5**. 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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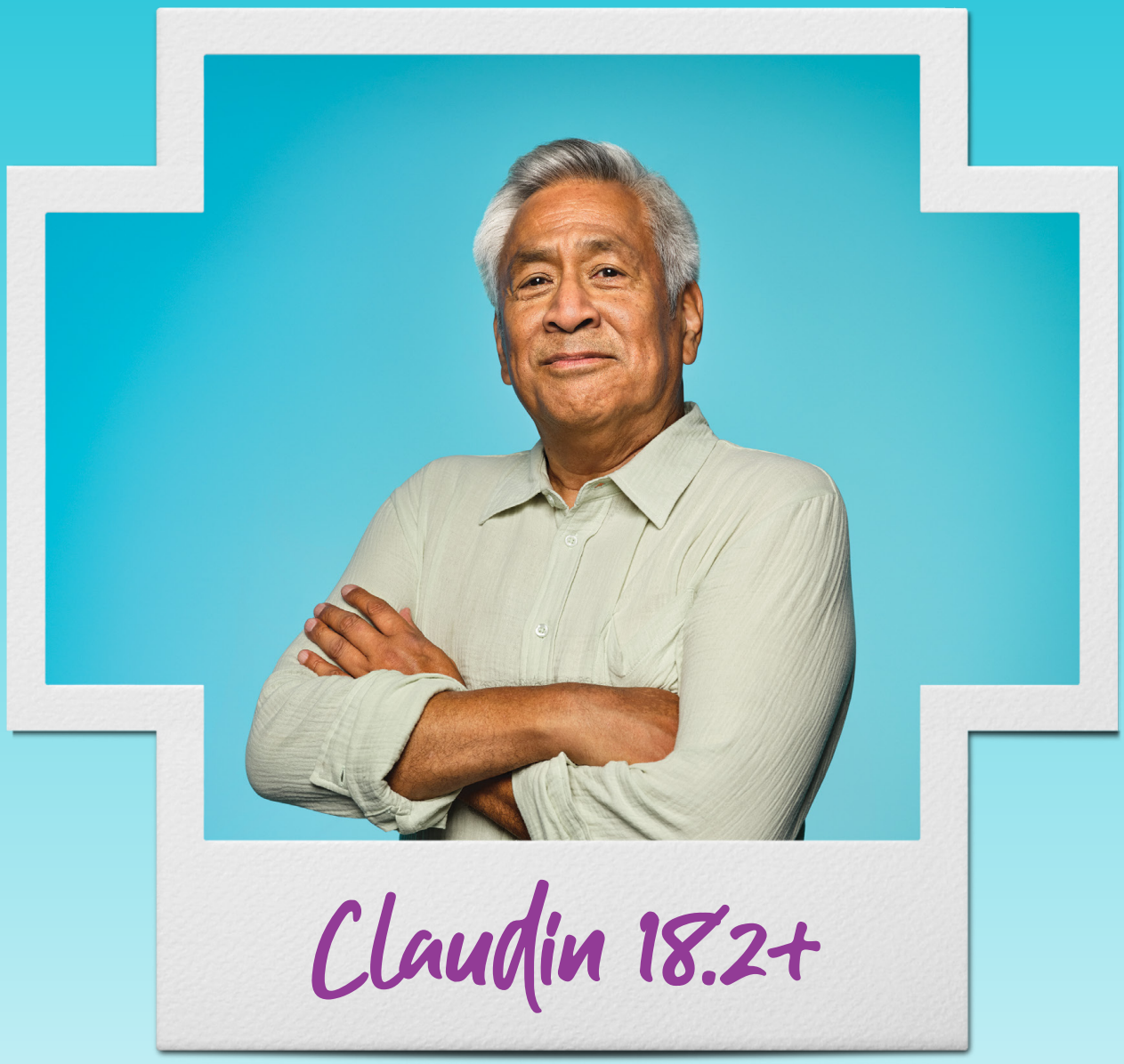

Claudin 18.2+

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