Guide for healthcare professionals treating CLL/SLL or AML

ORDERING VENCLEXTA® (venetoclax tablets) FOR NEW PATIENTS

CLL=chronic lymphocytic leukemia; SLL=small lymphocytic lymphoma; AML=acute myeloid leukemia.

Indications

VENCLEXTA is indicated:

- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
- In combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults:
  - 75 years or older, or
  - who have comorbidities that preclude use of intensive induction chemotherapy.

Select Important Safety Information

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).
- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA. The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during ramp-up phase, and requires VENCLEXTA dose reduction.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA. Monitor blood counts and for signs of infection; manage as medically appropriate.
- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Fatal and serious infections such as pneumonia and sepsis have occurred in patients with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution.
- Do not administer live attenuated vaccines prior to, during, or after treatment until B-cell recovery occurs.
- VENCLEXTA may cause embryo-fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

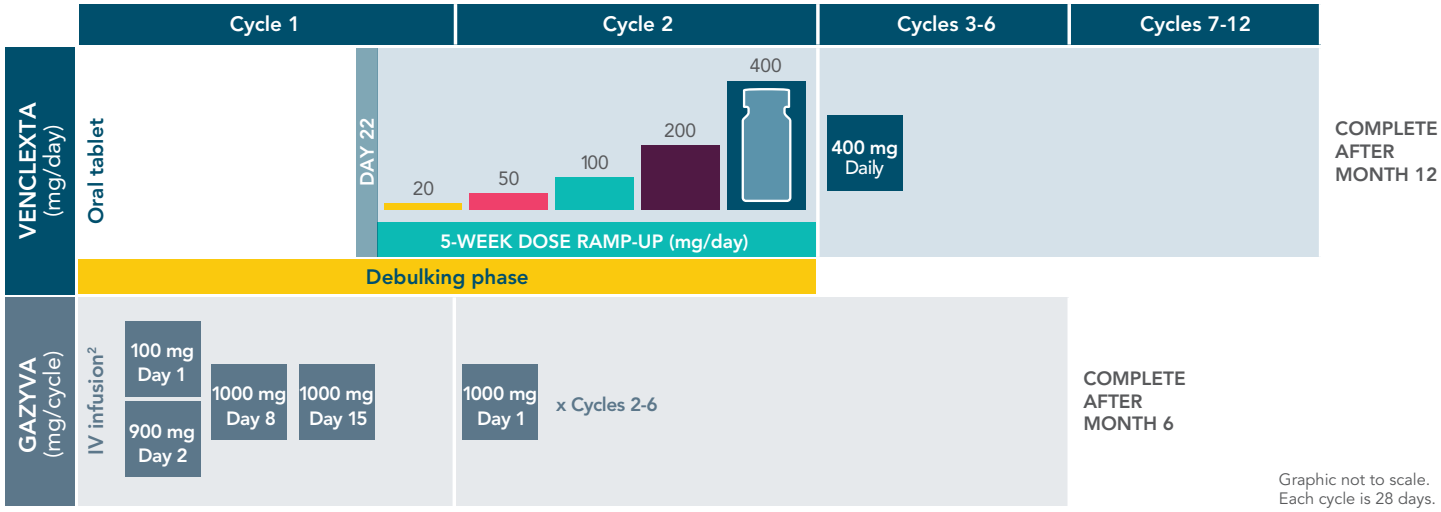
Please see additional Important Safety Information on pages 10 and 11.
Please see the full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

VENCLEXTA for 1L treatment of CLL/SLL[1]

VENCLEXTA + GAZYVA® (obinutuzumab) (VEN+G) dosing

On Cycle 1, Day 22, the VENCLEXTA 5-week dose ramp-up begins—upon ramp-up completion, the recommended dose for VENCLEXTA will continue until the last day of Cycle 12



Graphic not to scale.
Each cycle is 28 days.

- Start IV GAZYVA administration at 100 mg on Cycle 1, Day 1, followed by 900 mg on Cycle 1, Day 2. Administer 1000 mg on Days 8 and 15 of Cycle 1 and on Day 1 of each subsequent 28-day cycle, for a total of 6 cycles
  - Refer to the GAZYVA prescribing information for recommended GAZYVA dosing information
- On Cycle 1, Day 22, start oral VENCLEXTA according to the 5-week ramp-up schedule (Week 1: 20 mg once daily; Week 2: 50 mg once daily; Week 3: 100 mg once daily; Week 4: 200 mg once daily; Week 5: 400 mg once daily)
- After completing the ramp-up schedule on Cycle 2, Day 28, patients should continue VENCLEXTA 400 mg once daily from Cycle 3, Day 1 until the last day of Cycle 12

For complete dosing information, including risk assessment and prophylaxis for TLS and dose modifications, please see section 2 of the VENCLEXTA full Prescribing Information.

1L=first line; IV=intravenous; TLS=tumor lysis syndrome.

Select Important Safety Information

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).
- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA. The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during ramp-up phase, and requires VENCLEXTA dose reduction.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA. Monitor blood counts and for signs of infection; manage as medically appropriate.
- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Fatal and serious infections such as pneumonia and sepsis have occurred in patients with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution.
- Do not administer live attenuated vaccines prior to, during, or after treatment until B-cell recovery occurs.
- VENCLEXTA may cause embryo-fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

Please see additional Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

Ordering VEN+G for your 1L CLL/SLL patients[1,2]

Ordering VENCLEXTA[1]

To order, contact your specialty distributor (see page 8). VENCLEXTA is distributed through a limited distribution network.

For the first 4 weeks of treatment with VENCLEXTA, the CLL/SLL Starting Pack contains everything your patients need in 4 weekly wallet blister packs.

Individual wallets and unit-dose blister packs are also available for order, if necessary.

Recommended VENCLEXTA dosing configurations for CLL/SLL on pages 3 and 5

CLL/SLL Starting Pack for Weeks 1-4	Week 5 and beyond
	
NDC# 0074-0579-28	**NDC#** 0074-0576-22

When using an EMR ordering system, be sure to find and select the Starting Pack option.

Remember to order the 100-mg bottle in time for Week 5 dosing.

Dose modifications for use with CYP3A and P-gp inhibitors in CLL/SLL (recommended daily dose)

Concomitant medications	Step 1: Ramp-up					Step 2: Daily dose
	Week 1	Week 2	Week 3	Week 4	Week 5	Steady daily dose*
VENCLEXTA with POSACONAZOLE	Contraindicated during initiation and ramp-up phase					70 mg
VENCLEXTA with other STRONG CYP3A inhibitor	Contraindicated during initiation and ramp-up phase					100 mg
VENCLEXTA with MODERATE CYP3A inhibitor or P-gp inhibitor	10 mg	20 mg or less	50 mg or less	100 mg or less	200 mg or less	200 mg or less

*Consider alternative medications or reduce the VENCLEXTA dose as described in this table.
NDC=National Drug Code; EMR=electronic medical record; CYP3A=cytochrome P450 3A; P-gp=P-glycoprotein.

The recommended dosage of VENCLEXTA may be delivered using any of the approved tablet strengths.

Dosage modifications for patients with severe hepatic impairment

- Reduce the VENCLEXTA once daily dose by 50% for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more closely for adverse reactions

Ordering GAZYVA® (obinutuzumab)[2]:

NDC# 50242-070-01 (1000 mg/40-mL vial)

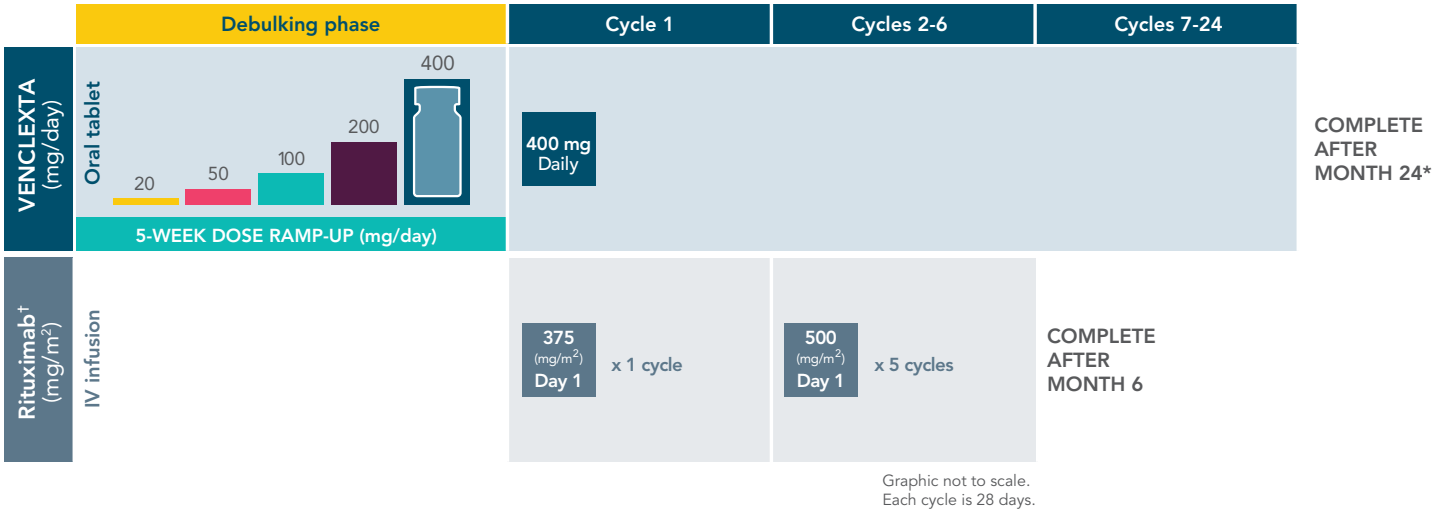
Please see additional Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA® venetoclax tablets 10mg, 50mg, 100mg

VENCLEXTA for treatment of R/R CLL/SLL[1]

VENCLEXTA + rituximab (VEN+R) dosing

VENCLEXTA is taken for 24 months from Cycle 1, Day 1 of rituximab, after the 5-week VENCLEXTA dose ramp-up



Graphic not to scale.
Each cycle is 28 days.

- To gradually reduce tumor burden (debulk) and decrease the risk of TLS, start with the 5-week VENCLEXTA dose ramp-up

For complete dosing information, including risk assessment and prophylaxis for TLS and dose modifications, please see section 2 of the VENCLEXTA full Prescribing Information.

*24 months from Cycle 1, Day 1 of rituximab.
†Start rituximab after patient has received the 400-mg dose of VENCLEXTA for 7 days.
R/R=relapsed/refractory.

Select Important Safety Information

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).
- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA. The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during ramp-up phase, and requires VENCLEXTA dose reduction.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA. Monitor blood counts and for signs of infection; manage as medically appropriate.
- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Fatal and serious infections such as pneumonia and sepsis have occurred in patients with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution.
- Do not administer live attenuated vaccines prior to, during, or after treatment until B-cell recovery occurs.
- VENCLEXTA may cause embryo-fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

Please see additional Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

Ordering VEN+R for your R/R CLL/SLL patients[1,3]

Ordering VENCLEXTA[1]

To order, contact your specialty distributor (see page 8). VENCLEXTA is distributed through a limited distribution network.

For the first 4 weeks of treatment with VENCLEXTA, the CLL/SLL Starting Pack contains everything your patients need in 4 weekly wallet blister packs.

Individual wallets and unit-dose blister packs are also available for order, if necessary.

Recommended VENCLEXTA dosing configurations for CLL/SLL on pages 3 and 5

CLL/SLL Starting Pack for Weeks 1-4	Week 5 and beyond
	
NDC# 0074-0579-28	**NDC#** 0074-0576-22

When using an EMR ordering system, be sure to find and select the Starting Pack option.

Remember to order the 100-mg bottle in time for Week 5 dosing.

Dose modifications for use with CYP3A and P-gp inhibitors in CLL/SLL (recommended daily dose)

Concomitant medications	Step 1: Ramp-up					Step 2: Daily dose
	Week 1	Week 2	Week 3	Week 4	Week 5	Steady daily dose*
VENCLEXTA with POSACONAZOLE	Contraindicated during initiation and ramp-up phase					70 mg
VENCLEXTA with other STRONG CYP3A inhibitor	Contraindicated during initiation and ramp-up phase					100 mg
VENCLEXTA with MODERATE CYP3A inhibitor or P-gp inhibitor	10 mg	20 mg or less	50 mg or less	100 mg or less	200 mg or less	200 mg or less

*Consider alternative medications or reduce the VENCLEXTA dose as described in this table.

The recommended dosage of VENCLEXTA may be delivered using any of the approved tablet strengths.

Dosage modifications for patients with severe hepatic impairment

- Reduce the VENCLEXTA once daily dose by 50% for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more closely for adverse reactions

Ordering RITUXAN® (rituximab)[3]:

NDC# 50242-051-21 (100 mg/10 mL)
NDC# 50242-053-06 (500 mg/50 mL)

Please see the Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA® venetoclax tablets 10mg, 50mg, 100mg

Ordering VENCLEXTA for your appropriate 1L AML patients[1]

To order any of the following, please contact a specialty pharmacy (SP) or specialty distributor (SD)

For complete dosing information, including more information on dose modifications, please see section 2 of the VENCLEXTA full Prescribing Information.

CONCOMITANT MEDICATIONS	RAMP-UP				STEADY DAILY DOSE
DOSING					
VENCLEXTA + azacitidine	Day 1	Day 2	Day 3		Steady Daily Dose
VENCLEXTA + decitabine	100 mg	200 mg	400 mg		400 mg
VENCLEXTA + low-dose cytarabine	Day 1	Day 2	Day 3	Day 4	Steady Daily Dose
	100 mg	200 mg	400 mg	600 mg	600 mg
DOSE MODIFICATIONS FOR USE WITH CYP3A AND P-gp INHIBITORS					
VENCLEXTA + azacitidine or decitabine or low-dose cytarabine with POSACONAZOLE	Day 1	Day 2	Day 3	Day 4	Steady Daily Dose
Reduce the VENCLEXTA steady daily dose to 70 mg	10 mg	20 mg	50 mg	70 mg	70 mg
VENCLEXTA + azacitidine or decitabine or low-dose cytarabine with other **STRONG** CYP3A inhibitor	Day 1	Day 2	Day 3	Day 4	Steady Daily Dose
Reduce the VENCLEXTA steady daily dose to 100 mg	10 mg	20 mg	50 mg	100 mg	100 mg
VENCLEXTA + azacitidine or decitabine with **MODERATE** CYP3A inhibitor or P-gp inhibitor	Day 1	Day 2	Day 3		Steady Daily Dose
Reduce the VENCLEXTA dose by at least 50%	50 mg or less	100 mg or less	200 mg or less		200 mg or less
VENCLEXTA + low-dose cytarabine with **MODERATE** CYP3A inhibitor or P-gp inhibitor	Day 1	Day 2	Day 3	Day 4	Steady Daily Dose
Reduce the VENCLEXTA dose by at least 50%	50 mg or less	100 mg or less	200 mg or less	300 mg or less	300 mg or less

The recommended dosage of VENCLEXTA may be delivered using any of the approved tablet strengths.

Please see the Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

Ordering VENCLEXTA for your appropriate 1L and R/R CLL/SLL and 1L AML patients[1]

To order any of the following, please contact a specialty pharmacy (SP) or specialty distributor (SD)

For complete dosing information, including more information on dose modifications, please see section 2 of the VENCLEXTA full Prescribing Information.

Dosage modifications for patients with severe hepatic impairment

- Reduce the VENCLEXTA once daily dose by 50% for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more closely for adverse reactions

Unit doses and wallets for dose modifications during treatment initiation and steady daily dose are available for both CLL/SLL and AML

10-mg unit dose (x2):
NDC# 0074-0561-11

10-mg wallet (14 tablets):
NDC# 0074-0561-14

50-mg unit dose:
NDC# 0074-0566-11

50-mg wallet (7 tablets):
NDC# 0074-0566-07

100-mg unit dose:
NDC# 0074-0576-11

100-mg bottle (28 ct):
NDC# 0074-0576-30

100-mg bottle (120 ct):
NDC# 0074-0576-22

Store in original container at or below 86 °F (30 °C) to protect from moisture. Dispense to patient in original container to protect from moisture.

Please see the Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

Specialty pharmacies and distributors

The following network of SPs and SDs are authorized to dispense VENCLEXTA. This network will assist providers and patients in obtaining VENCLEXTA. To see the distribution network for GAZYVA® (obinutuzumab) and RITUXAN® (rituximab), visit genentech-access.com.

	Name	Phone	Fax	Website
Distributors for authorized specialty pharmacies, physicians' offices, and hospitals (pharmacy dispensed)	Amerisource Bergen Specialty Distribution **fka:** ASD Healthcare	800-746-6273	800-547-9413	asdhealthcare.com
	Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	614-553-6301	specialtyonline.cardinalhealth.com
	McKesson Plasma and Biologics (MPB)	877-625-2566	888-752-7626	connect.mckesson.com
	McKesson Specialty Health	800-482-6700	800-289-9285	mscs.mckesson.com
	Oncology Supply	800-633-7555	800-248-8205	oncologysupply.com
Specialty pharmacies	Biologics by McKesson	800-850-4306 Option 2	800-823-4506	biologics.mckesson.com
	Onco360 Oncology Pharmacy	877-662-6633	877-662-6355	onco360.com
	Optum Specialty **fka:** Avella & Diplomat	877-445-6874	877-342-4596	specialty.optumrx.com
Distributors for closed system/federal accounts	Amerisource Bergen Specialty Distribution **fka:** ASD Healthcare	800-746-6273	800-547-9413	asdhealthcare.com
	Cardinal Health Specialty Pharmaceutical Distribution	855-855-0708	614-553-6301	specialtyonline.cardinalhealth.com
	McKesson Plasma and Biologics (MPB)	877-625-2566	888-752-7626	connect.mckesson.com
Authorized Distributors for Puerto Rico	Alivia Specialty, LLC	888-925-1989 787-925-1999	787-925-1015 787-723-6987	www.aliviahealth.com/specialty
	Cardinal Health Puerto Rico	787-625-4100	787-625-4398	www.cardinalhealth.pr
	Special Care Pharmacy Services, LLC	787-781-4585 877-899-8997 888-727-1727	787-783-2951 855-230-9963	www.specialcarepr.com

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Please see the Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

Stocking and pricing information of VENCLEXTA

	Unit information				Case information				Ordering code	Pricing
	Package unit	Package size	Dimensions by unit	Unit weight	Case quantity	Case cube	Dimensions by case	Case weight	NDC#[1]	List/each*
CLL/SLL Starting Pack	Carton	14 x 10-mg tablets 7 x 50-mg tablets 7 x 100-mg tablets 14 x 100-mg tablets	D: 6.5" H: 2.63" W: 6.22"	0.87 lb	4	0.37 cu ft	D: 13.63" H: 7.19" W: 6.44"	3.93 lb	0074-0579-28	<variable>
10-mg wallet	Carton	14 x 10-mg tablets	D: 1.13" H: 6" W: 4.06"	0.21 lb	10	0.24 cu ft	D: 12.64" H: 5" W: 6.65"	2.48 lb	0074-0561-14	<variable>
50-mg wallet	Carton	7 x 50-mg tablets	D: 1.13" H: 6" W: 4.06"	0.21 lb	10	0.24 cu ft	D: 12.64" H: 5" W: 6.65"	2.48 lb	0074-0566-07	<variable>
100-mg bottle (28 ct)	Bottle	28 x 100-mg tablets	D: 2.75" H: 4.50" W: 2.50"	0.20 lb	12	0.26 cu ft	D: 11.63" H: 4.88" W: 8"	2.77 lb	0074-0576-30	<variable>
100-mg bottle (120 ct)	Bottle	120 x 100-mg tablets	D: 2.63" H: 4.44" W: 2.38"	0.43 lb	12	0.27 cu ft	D: 11.31" H: 5.38" W: 7.75"	5.62 lb	0074-0576-22	<variable>
10-mg unit dose	Carton	2 x 10-mg tablets	D: 1.25" H: 3" W: 3.88"	0.07 lb	36	0.44 cu ft	D: 16" H: 3.75" W: 12.75"	3.33 lb	0074-0561-11	<variable>
50-mg unit dose	Carton	1 x 50-mg tablet	D: 1.25" H: 3" W: 3.88"	0.07 lb	36	0.44 cu ft	D: 16" H: 3.75" W: 12.75"	3.36 lb	0074-0566-11	<variable>
100-mg unit dose	Carton	1 x 100-mg tablet	D: 1.25" H: 3" W: 3.88"	0.07 lb	36	0.44 cu ft	D: 16" H: 3.75" W: 12.75"	3.40 lb	0074-0576-11	<variable>

*List price is the price for this drug submitted to certain pricing compendia in <Month Year> for publication with respect to customers, other than wholesalers, that purchase less than one case and does not include prompt-pay discounts or other discounts, rebates, or reductions in price. The actual price paid by customers and retail price paid by consumers at a pharmacy may vary.

Please see the Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

Important Safety Information

Contraindication

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up phase is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).

Tumor Lysis Syndrome

- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients, and during reinitiation after dosage interruption in patients with CLL/SLL. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase. TLS, including fatal cases, has been reported after a single 20 mg dose.
- In patients with CLL/SLL who followed the current (5 week) dose ramp-up and the TLS prophylaxis and monitoring measures, the rate of TLS was 2% in the VENCLEXTA CLL/SLL monotherapy trials. The rate of TLS remained consistent with VENCLEXTA in combination with obinutuzumab or rituximab. With a 2- to 3-week dose ramp-up and higher starting dose in patients with CLL/SLL, the TLS rate was 13% and included deaths and renal failure.
- In patients with AML who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 1.1% in patients who received VENCLEXTA in combination with azacitidine. In patients with AML who followed a 4-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine.
- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Splenomegaly may also increase the risk of TLS in patients with CLL/SLL.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

Neutropenia

- In patients with CLL, Grade 3 or 4 neutropenia developed in 63% to 64% of patients and Grade 4 neutropenia developed in 31% to 33% of patients treated with VENCLEXTA in combination and monotherapy studies. Febrile neutropenia occurred in 4% to 6% of patients.
- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Monitor complete blood counts. Interrupt dosing for severe neutropenia. In CLL, resume at same or reduced dose. In AML, resume at same dose then reduce duration based on remission status and first or subsequent occurrence of neutropenia. Consider supportive measures including antimicrobials and growth factors (e.g., G-CSF).

Infections

- Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution and resume at same or reduced dose.

Immunization

- Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until B-cell recovery occurs. Advise patients that vaccinations may be less effective.

Embryo-Fetal Toxicity

- VENCLEXTA may cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

Increased Mortality in Patients with Multiple Myeloma when VENCLEXTA is Added to Bortezomib and Dexamethasone

- In a randomized trial (BELLINI; NCT02755597) in patients with relapsed or refractory multiple myeloma, the addition of VENCLEXTA to bortezomib plus dexamethasone, a use for which VENCLEXTA is not indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with VENCLEXTA in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.

Please see additional Important Safety Information on page 11.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

Adverse Reactions

- **In patients with CLL receiving combination therapy with obinutuzumab,** serious adverse reactions were most often due to febrile neutropenia and pneumonia (5% each). The most common adverse reactions (≥20%) of any grade were neutropenia (60%), diarrhea (28%), and fatigue (21%). Fatal adverse reactions that occurred in the absence of disease progression and with onset within 28 days of the last study treatment were reported in 2% (4/212) of patients, most often from infection.
- **In patients with CLL receiving combination therapy with rituximab,** the most frequent serious adverse reaction (≥5%) was pneumonia (9%). The most common adverse reactions (≥20%) of any grade were neutropenia (65%), diarrhea (40%), upper respiratory tract infection (39%), fatigue (22%), and nausea (21%). Fatal adverse reactions that occurred in the absence of disease progression and within 30 days of the last VENCLEXTA treatment and/or 90 days of the last rituximab were reported in 2% (4/194) of patients.
- **In patients with CLL/SLL receiving monotherapy,** the most frequent serious adverse reactions (≥5%) were pneumonia (9%), febrile neutropenia (5%), and sepsis (5%). The most common adverse reactions (≥20%) of any grade were neutropenia (50%), diarrhea (43%), nausea (42%), upper respiratory tract infection (36%), anemia (33%), fatigue (32%), thrombocytopenia (29%), musculoskeletal pain (29%), edema (22%), and cough (22%). Fatal adverse reactions that occurred in the absence of disease progression and within 30 days of venetoclax treatment were reported in 2% of patients in the VENCLEXTA monotherapy studies, most often (2 patients) from septic shock.
- **In patients with AML receiving combination therapy with azacitidine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia (30%), pneumonia (22%), sepsis (excluding fungal; 19%), and hemorrhage (6%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (98%), platelets decreased (94%), lymphocytes decreased (91%), hemoglobin decreased (61%), nausea (44%), diarrhea (43%), febrile neutropenia (42%), musculoskeletal pain (36%), pneumonia (33%), fatigue (31%), and vomiting (30%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with azacitidine, with the most frequent (≥2%) being pneumonia (4%), sepsis (excluding fungal; 3%), and hemorrhage (2%).
- **In patients with AML receiving combination therapy with decitabine,** the most frequent serious adverse reactions (≥10%) were sepsis (excluding fungal; 46%), febrile neutropenia (38%), and pneumonia (31%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (100%), lymphocytes decreased (100%), white blood cells decreased (100%), platelets decreased (92%), hemoglobin decreased (69%), febrile neutropenia (69%), fatigue (62%), constipation (62%), musculoskeletal pain (54%), dizziness (54%), nausea (54%), abdominal pain (46%), diarrhea (46%), pneumonia (46%), sepsis (excluding fungal; 46%), cough (38%), pyrexia (31%), hypotension (31%), oropharyngeal pain (31%), edema (31%), and vomiting (31%). One (8%) fatal adverse reaction of bacteremia occurred within 30 days of starting treatment.
- **In patients with AML receiving combination therapy with low-dose cytarabine,** the most frequent serious adverse reactions (≥10%) were pneumonia (17%), febrile neutropenia (16%), and sepsis (excluding fungal; 12%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were platelets decreased (97%), neutrophils decreased (95%), lymphocytes decreased (92%), hemoglobin decreased (63%), nausea (42%), and febrile neutropenia (32%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with LDAC, with the most frequent (≥5%) being pneumonia (6%) and sepsis (excluding fungal; 7%).

Drug Interactions

- Concomitant use with a P-gp inhibitor or a strong or moderate CYP3A inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Consider alternative medications or adjust VENCLEXTA dosage and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a P-gp inhibitor or a strong or moderate CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.
- Patients should avoid grapefruit products, Seville oranges, and starfruit during treatment as they contain inhibitors of CYP3A.
- Avoid concomitant use of strong or moderate CYP3A inducers.
- Monitor international normalized ratio (INR) more frequently in patients receiving warfarin.
- Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA.

Lactation

- Advise nursing women not to breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.
- Based on findings in animals, VENCLEXTA may impair male fertility.

Hepatic Impairment

- Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for adverse reactions. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Please see additional Important Safety Information on page 10.
Please see full Prescribing Information.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

VENCLEXTA PATIENT SUPPORT PROGRAMS

VENCLEXTA Access Solutions

VENCLEXTA Access Solutions is your resource for helpful access and reimbursement support.

(866) 422-2377 | **Genentech-Access.com/VENCLEXTA**

The Genentech Oncology Co-pay Assistance Program

Genentech co-pay programs provide financial assistance to eligible commercially insured patients to help with their co-pays, co-insurance or other out-of-pocket (OOP) costs.*

(855) MY-COPAY/(855) 692-6729 | **CopayAssistanceNow.com**

*Eligibility criteria apply. Not valid for patients using federal or state government programs to pay for their medications and/or administration of their Genentech medication. Patient must be taking the Genentech medication for an FDA-approved indication. See full Terms and Conditions at **CopayAssistanceNow.com**.

Genentech Patient Foundation

If patients don't have insurance coverage or have financial concerns and meet eligibility criteria, they may be able to get free VENCLEXTA from the Genentech Patient Foundation.

(888) 941-3331 | **Genentechpatientfoundation.com**

Genentech provides coverage and reimbursement services to help patients understand benefits, coverage and reimbursement. Genentech provides these services to patients only after a health care provider has prescribed a Genentech product. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and health care provider. Genentech and AbbVie make no representation or guarantee concerning coverage or reimbursement for any service or item. Genentech reserves the right to modify or discontinue the program at any time and to verify the accuracy of information submitted.

To be eligible for free VENCLEXTA from the Genentech Patient Foundation, insured patients who have coverage for their medicine should try to pursue other forms of financial assistance, if available, and meet certain income requirements. Uninsured patients and insured patients without coverage for their medicine must meet a different set of income requirements.

Contact your AbbVie or Genentech representative

to learn more about VENCLEXTA or ask questions about treatment initiation

References: 1. VENCLEXTA Prescribing Information. **2.** GAZYVA Prescribing Information. **3.** RITUXAN Prescribing Information.

Please see the Important Safety Information on pages 10 and 11.
Please see full Prescribing Information.

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