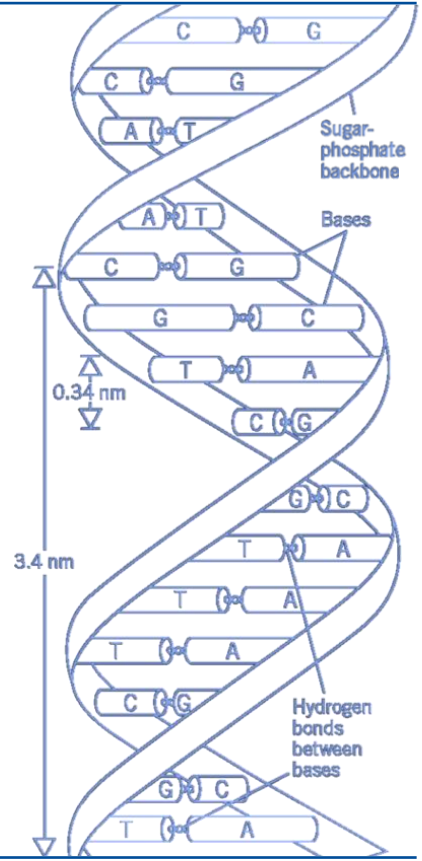
VENETOCLAX DISPENSING GUIDE



This is a medical resource for scientific information and is intended for healthcare providers practicing in the United States.

Current as of July 2024

Genentech
A Member of the Roche Group

Veeva Document Number # (version #)

INDICATIONS

CLL/SLL

INDICATIONS AND USAGE

Venetoclax is a BCL-2 inhibitor indicated:

For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

In combination with Obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL)

In combination with rituximab for the treatment of adult patients with CLL who have received at least one prior therapy

AML

INDICATIONS AND USAGE

Venetoclax is a BCL-2 inhibitor indicated:

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

Venclexta Prescribing Information, June 2022.

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STORE IN ORIGINAL CONTAINER AT OR BELOW 86°F (30°C). DISPENSE TO PATIENT IN ORIGINAL CONTAINER TO PROTECT FROM MOISTURE. ADVISE PATIENTS TO KEEP VENETOCLAX IN ORIGINAL CONTAINER.

Venetoclax is supplied as the following film-coated tablets

10 mg
Film coated tablets are round, biconvex shaped, pale yellow debossed with “V” on one side and “10” on the other side

50 mg
Film coated tablets are oblong, biconvex shaped, beige debossed with “V” on one side and “50” on the other side

100 mg
Film coated tablets are oblong, biconvex shaped, pale yellow debossed with “V” on one side and “100” on the other side

Venetoclax is supplied as the following packages

Dose-Escalation Starter Pack (CLL/SLL only)

Each pack contains 4 weekly wallet blister packs:

- Week 1 (14 × 10-mg tablets)
- Week 2 (7 × 50-mg tablets)
- Week 3 (7 × 100-mg tablets)
- Week 4 (14 × 100-mg tablets)

Bottles for Steady-State Dose

- 120 × 100-mg tablets
- 28 × 100-mg tablets

Wallets and Blister Packs for Replacement or Special Schedule Dosing

- Wallet: 14 × 10-mg
- Wallet: 7 × 50-mg
- Blister pack: 2 × 10-mg
- Blister pack: 1 × 50-mg
- Blister pack: 1 × 100-mg (unit dose)

VENCLEXTA Prescribing Information AbbVie Inc & Genentech Inc; June 2022. CLL=Chronic Lymphocytic Leukemia. SLL=Small Lymphocytic Lymphoma.
Venclexta Prescribing Information, June 2022.

DISPENSING VENETOCLAX: EXAMPLES OF CLINICAL SCENARIOS

Below are examples of dispensing scenarios by package size based on the venetoclax daily dose. Please refer to the Venclexta package insert for full dosing guidance.

 **Dose-Escalation Starter Pack (CLL/SLL only)**	• **CLL New Patient Ramp Up**
 **120 count bottle (100mg)**	• **CLL Dose at Steady-State** (400mg/day) • **AML Dose at Steady-State** (400mg/day)
 **28 count bottle (100mg)**	• **AML New Patient Ramp Up standard dose per PI** • **CLL** / **AML Management:** Adverse events requiring dose holds or dose reductions • **CLL** / **AML Drug Interactions:** Steady-state venetoclax dose with a strong or moderate CYP3A inhibitor, or P-gp inhibitor
 **Wallet & Blister Packs**	• **AML New Patient Ramp-up with dose reductions due to DDI's** • **CLL Therapy Restart:** TLS reassessment • **CLL** / **AML Management:** Adverse events requiring dose holds or dose reductions • **CLL** / **AML Drug Interactions:** i.e. Posaconazole (70mg venetoclax dose) • **CLL** / **AML** Quantity dispensed per prescription < 28 count

AML=Acute Myeloid Leukemia. CLL=Chronic Lymphocytic Leukemia. CYP3A=Cytochrome P450 3A4. DDI=Drug-drug interactions. P-gp=p-glycoprotein. PI=Prescribing Information. SLL=Small Lymphocytic Lymphoma.

Venclexta Prescribing Information, June 2022.

VENETOCLAX DISPENSING GUIDE*: QUANTITY BY DOSE, TREATMENT DURATION, AND PACKAGE SIZES

Venetoclax is supplied as the following film-coated tablets

10 mg
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50 mg
Film coated tablets are oblong, biconvex shaped, beige debossed with “V” on one side and “50” on the other side

100 mg
Film coated tablets are oblong, biconvex shaped, pale yellow debossed with “V” on one side and “100” on the other side

Store in original container at or below 86°F (30°C). Dispose to patient in original container to protect from moisture. Advise patients to keep VENCLEXTA in original container.

Venetoclax Package Size Presentation		National Drug Code
Wallet:	14 x 10 mg tablets	0074-0561-14
	7 x 50 mg tablets	0074-0566-07
Unit Dose Blister:	2 x 10 mg tablets	0074-0561-11
	1 x 50 mg tablets	0074-0566-11
	1 x 100 mg tablets	0074-0576-11
Bottle:	28 x 100 mg tablets	0074-0576-30
	120 x 100 mg tablets	0074-0576-22
Starting Pack (for CLL/SLL ONLY)		0074-0579-28

*Guide is not all inclusive of dosing scenarios Venclexta Prescribing Information, June 2022..

Venetoclax Dose (Steady-State)	Treatment Duration	Quantity to Dispense	Package Size Quantity
70 mg  Plus	7 Days	7 x 50 mg 14 x 10 mg	1 x 50 mg Wallet 1 x 10 mg Wallet
	14 Days	14 x 50 mg 28 x 10 mg	2 x 50 mg Wallet 2 x 10 mg Wallet
	21 Days	21 x 50 mg 42 x 10 mg	3 x 50 mg Wallet 3 x 10 mg Wallet
	28 Days	28 x 50 mg 56 x 10 mg	4 x 50 mg Wallet 4 x 10 mg Wallet
100 mg 	7 Days	7	7 x Unit Dose
	14 Days	14	14 x Unit Dose
	21 Days	21	21 x Unit Dose
	28 Days	28	1 x 28 Count Bottle
200 mg 	7 Days	14	14 Unit Dose
	14 Days	28	1 x 28 Count Bottle
	21 Days	42	42 Unit Dose OR 14 x Unit Dose + 1 x 28 Count Bottle
	28 Days	56	2 x 28 Count Bottle
300 mg 	7 Days	21	21 Unit Dose
	14 Days	42	42 Unit Dose OR 14 x Unit Dose + 1 x 28 Count Bottle
	21 Days	63	63 Unit Dose OR 7 x Unit Dose + 2 x 28 Count Bottle
	28 Days	84	3 x 28 Count Bottle
400 mg 	7 Days	28	1 x 28 Count Bottle
	14 Days	56	2 x 28 Count Bottle
	21 Days	84	3 x 28 Count Bottle
	28 Days	112	4 x 28 Count Bottle
	30 Days	120	1 x 120 Count Bottle

VENETOCLAX SAFETY OVERVIEW

Contraindication

- **Strong CYP3A Inhibitors:** Concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase in patients with CLL/SLL is contraindicated.

Warnings and Precautions

- **TLS:** Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in patients treated with venetoclax. Anticipate TLS; assess risk in all patients. Premedicate with anti-hyperuricemics and ensure adequate hydration. Employ more intensive measures (intravenous hydration, frequent monitoring, hospitalization) as overall risk increases.
- **Neutropenia:** Monitor blood counts. Interrupt dosing and resume at same or reduced dose. Consider supportive care measures.
- **Infections:** Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with venetoclax. Monitor for signs and symptoms of infection and treat promptly. Withhold venetoclax 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 venetoclax treatment until B-cell recovery.
- **Embryo-Fetal Toxicity:** May cause embryo-fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

Warnings and Precautions (continued...)

- **Increased mortality in patients with multiple myeloma (MM) when venetoclax is added to bortezomib and dexamethasone.** In a randomized trial in patients with relapsed or refractory MM, the addition of venetoclax to bortezomib plus dexamethasone, a use for which venetoclax is not indicated, resulted in increased mortality. Treatment of patients with MM with venetoclax in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.

Adverse Reactions

- In **CLL/SLL**, the most common adverse reactions (≥20%) for venetoclax when given in combination with obinutuzumab or rituximab or as monotherapy were neutropenia, thrombocytopenia, anemia, diarrhea, nausea, upper respiratory tract infection, cough, musculoskeletal pain, fatigue, and edema.
- In **AML**, the most common adverse reactions (≥30%) in combination with azacitidine, or decitabine, or low-dose cytarabine were nausea, diarrhea, thrombocytopenia, constipation, neutropenia, febrile neutropenia, fatigue, vomiting, edema, pyrexia, pneumonia, dyspnea, hemorrhage, anemia, rash, abdominal pain, sepsis, musculoskeletal pain, dizziness, cough, oropharyngeal pain, and hypotension.

Review full prescribing information for additional information or contact Genentech Medical Information at 1-800-821-8590 or go to https://www.gene.com/contact-us/submit-medical-inquiry.

Venclexta Prescribing Information, June 2022.

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THANK YOU