

A GUIDE TO HELP YOU MAKE THE MOST OF YOUR  
CONVERSATIONS WITH PATIENTS ABOUT THEIR AML TREATMENT

This piece covers both VEN+HMA and VEN+LDAC  
(not approved in EU). Please review and adjust  
according to local label. As always, this can't be  
used before full local MRLO review

# STARTING RIGHT WITH VENCLYXTO

venetoclax film coated tablets

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placeholder for safety statement, as per local regulation.]

- ▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

AML=acute myeloid leukaemia.

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 **VENCLYXTO** ▼  
venetoclax film coated tablets



AML  
OVERVIEW

VENCLYXTO  
OVERVIEW

VENCLYXTO  
DOSING FOR AML

VENCLYXTO  
ADMINISTRATION INSTRUCTIONS

WHAT TO EXPECT WITH  
VENCLYXTO TREATMENT

STAYING ON TRACK WITH  
VENCLYXTO TREATMENT

# USING THIS TOOL

## Objective

The AML right start dialogue tool is designed to support the conversations you have with your patients and their caregivers about AML and treatment with VENCLYXTO. This piece will:

- Help them understand their AML diagnosis
- Guide them through treatment initiation with VENCLYXTO
- Ensure they have the information they need to follow VENCLYXTO treatment as prescribed

## Instructions for use

This clickable PDF can be used by scrolling through page by page or clicking to different sections. Provided throughout as overlays for each section are key points, additional contextual background, and suggestions for enhancing the dialogue.

Click the speech bubble icon  at the top left of the screen to access these overlays.

**This tool is for electronic use by healthcare professionals only. It must not be distributed in any format to patients.**

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AML  
OVERVIEW

VENCLYXTO  
OVERVIEW

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DOSING FOR AML

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WHAT TO EXPECT WITH  
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STAYING ON TRACK WITH  
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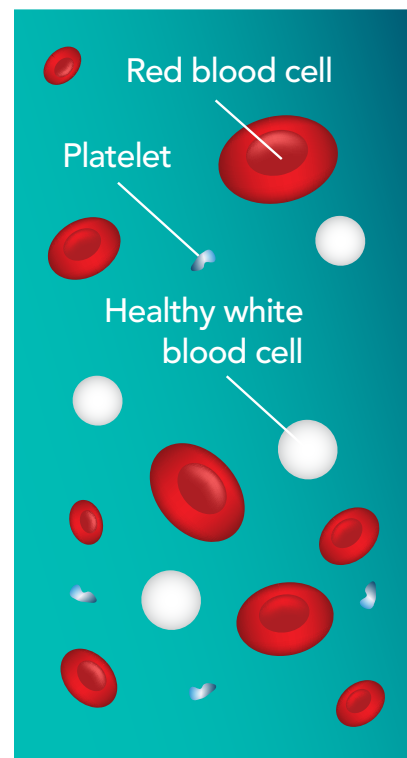
## WHAT IS AML?

**AML is a type of cancer that affects your ability to make working myeloid cells**, a type of blood cell. Myeloid cells are in your bone marrow, where new blood cells, including red blood cells, white blood cells, and platelets, are made.

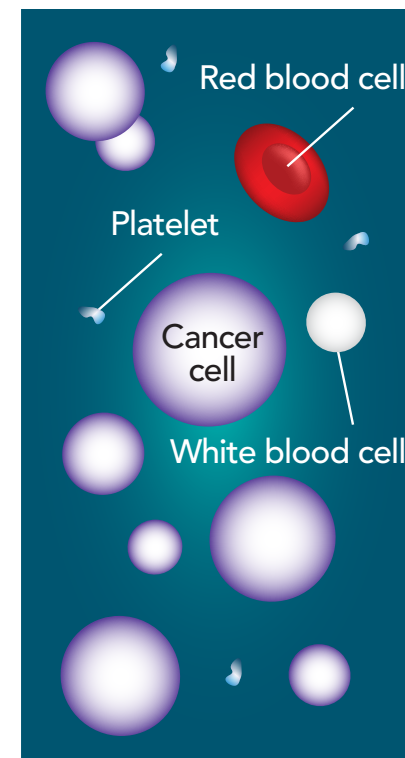
When you have AML, your body overproduces immature blood cells, which crowd out healthy red blood cells, white blood cells, and platelets in your bone marrow. As a result, people with AML may experience infection, anaemia, or easy bleeding.

An AML diagnosis is often unexpected and abrupt, so it may be difficult to process all of the information.

HEALTHY BONE MARROW

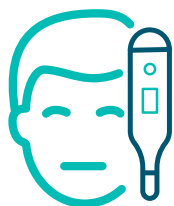


AML BONE MARROW



Blood cells and platelets not actual size.

## WHAT IS AML? (CONT'D)



Without enough healthy white blood cells, your body's ability to fight infection is reduced and **you may develop flu-like symptoms, including fever and chills.**



Without enough healthy red blood cells and platelets, **you may feel tired. You also may require blood transfusions and bruise or bleed more easily.**



The way AML affects your blood makes it essential to **start receiving treatment and to stay on therapy as instructed by your doctor** (typically until your AML gets worse or you can no longer tolerate therapy).

One of the main goals of AML treatment is to restore the balance of your blood cells by reducing the number of abnormal or leukaemic cells in your bone marrow.

## WHAT IS AML?

### Key point

- AML is a blood cancer that causes the body to make abnormal blood cells that may multiply quickly<sup>1,2</sup>

### Adding context

- The most common acute leukaemia in adults is AML<sup>3,4</sup>
- Multiple genetic mutations can be present in AML, and your patients' genetic profiles can evolve over the course of the disease and treatment<sup>5,6</sup>

### Suggestions to enhance the dialogue

- Take this opportunity to ensure patients and their caregivers understand:
  - The aggressive nature of their disease
  - The importance of treating early, identifying appropriate treatment, and staying on therapy until disease progression or it is no longer tolerated by the patient
- AML progresses rapidly, which means treatment decisions are typically made quickly. This mutual understanding can help to set up your discussion about treatment expectations

**REFERENCES:** 1. Döhner H, Weisdorf D, Bloomfield C. Acute myeloid leukemia. *N Engl J Med.* 2015;373(12):1136-1152. 2. Hanahan D, Weinberg RA. The hallmarks of cancer. *Cell.* 2000;100(1):57-70. 3. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. *CA Cancer J Clin.* 2019;69(1):7-34. 4. Adult Acute Myeloid Leukemia Treatment (PDQ®)—Patient Version. National Cancer Institute. Updated March 6, 2020. Accessed July 23, 2021. <https://www.cancer.gov/types/leukemia/patient/adult-aml-treatment-pdq#:~:text=Treatment%20of%20Adult%20Acute%20Myeloid%20Leukemia%20in%20Remission,-For%20information%20about&text=Combination%20chemotherapy,.clinical%20trial%20of%20arsenic%20trioxide>. 5. Ding L, Ley TJ, Larson DE. Clonal evolution in relapsed acute myeloid leukemia revealed by whole genome sequencing. *Nature.* 2012;481(7382):506-510. 6. Patel JP, Gönen M, Figueroa ME, et al. Prognostic relevance of integrated genetic profiling in acute myeloid leukemia. *N Engl J Med.* 2012;366(12):1079-1089.

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### WHAT IS VENCLYXTO?



Image of a single tablet is for demonstration purposes only.  
Not actual size.

VENCLYXTO (venetoclax film-coated tablets) is an **oral prescription medicine available in a tablet**. It is prescribed, in combination with other medicines, to adults with newly diagnosed AML.



## WHAT IS VENCLYXTO? (CONT'D)



VENCLYXTO is **taken once a day**.

You will receive it along with one of the following other treatments, which are administered as injections:

- Azacitidine (AZA)
- Decitabine (DEC)
- Low-dose cytarabine (LDAC)

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Please see the US PI for full safety information regarding LDAC.





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## WHAT IS VENClyXTO?

### Key point

- VENClyXTO is an oral medicine that is used to treat AML in patients who are ineligible for intensive chemotherapy<sup>1,2</sup>

### Adding context

- Patients with AML who are ineligible for intensive chemotherapy can be prescribed VENClyXTO in combination with a hypomethylating agent (HMA), including azacitidine (AZA) and decitabine (DEC),<sup>1</sup> or low-dose cytarabine (LDAC)<sup>2</sup>

### Suggestions to enhance the dialogue

- Explain why VENClyXTO was chosen to treat their AML
- It is important for patients to understand that they will take VENClyXTO along with another treatment
- Tell patients to consult their package leaflet containing the full VENClyXTO information

**REFERENCES:** 1. VENClyXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021. 2. VENCLEXTA. Prescribing information. AbbVie Inc; 2020.

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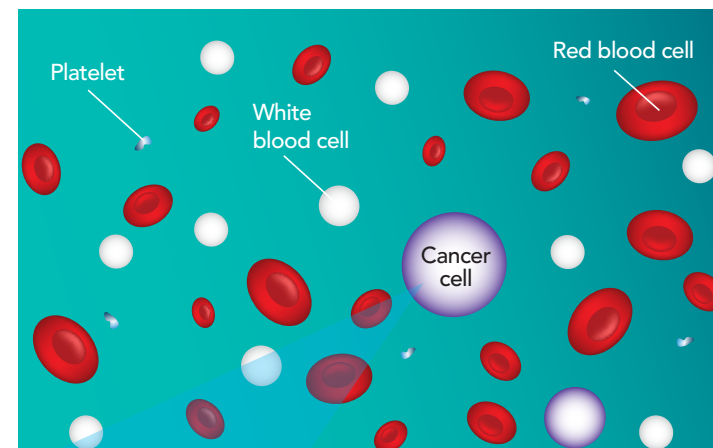
## HOW DOES VENCLYXTO WORK?

Normal cells in your body contain proteins, one of which is called BCL-2 (B-cell lymphoma 2). AML cells make too many BCL-2 proteins, which helps the cancer cells survive.

VENCLYXTO works by blocking BCL-2 proteins in cancer cells.

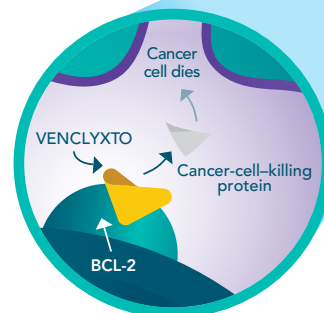
The blocking of BCL-2 proteins helps kill the cancer cell, thereby reducing the number of cancer cells in your body.

### Bone marrow after treatment with VENCLYXTO



Cells and platelets not actual size.

### Inside the cancer cell



## HOW DOES VENCLYXTO WORK?

### Key point

- VENCLYXTO is a BCL-2 inhibitor that targets a key hallmark of cancer by inducing apoptosis in AML cells<sup>1</sup>

### Adding context

- Overexpressed BCL-2 allows AML cells to evade apoptosis by sequestering pro-apoptotic proteins, preventing them from signalling the cell to die<sup>1-3</sup>
- VENCLYXTO selectively binds to BCL-2 to displace pro-apoptotic proteins, triggering events that lead to apoptosis<sup>1,3</sup>

### Suggestions to enhance the dialogue

- Describe how VENCLYXTO works: by targeting and blocking BCL-2 proteins. Once VENCLYXTO is attached, it helps restore the process of apoptosis, allowing cancer cells to die

**REFERENCES:** 1. VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021. 2. Anderson MA, Huang D, Roberts A. Targeting BCL2 for the treatment of lymphoid malignancies. *Semin Hematol.* 2014;51(3):219-227. 3. Souers AJ, Levenson JD, Boghaert ER, et al. ABT-199, a potent and selective BCL-2 inhibitor, achieves antitumor activity while sparing platelets. *Nat Med.* 2013;19(2):202-210.

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## RAMP-UP DOSING

Your healthcare team will start you on a low dose of VENCLYXTO, which you will take in combination with AZA, DEC, or LDAC. **Your VENCLYXTO dose will be increased each day for 3 to 4 days** until you reach your recommended dose, unless your healthcare team determines otherwise.

### VENCLYXTO DOSING\* (ONCE DAILY)

#### When used with AZA or DEC<sup>1</sup>

Day 1   
Day 2    
Day 3      
Days 4-28      
Total recommended daily dose is 400 mg

#### When used with LDAC<sup>2</sup>

Day 1   
Day 2    
Day 3      
Day 4        
Days 5-28        
Total recommended daily dose is 600 mg

\*Or as directed by your healthcare team.  
Images of tablets are for demonstration purposes only. Not actual size.

**NOTE:** It is very important that you stay well hydrated when taking VENCLYXTO, especially when you start treatment and increase your dose. Drinking water helps remove the breakdown of cancer cells from your blood through your urine. Your doctor may also give you other medicines to reduce the uric acid in your blood.

REFERENCES: 1. VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021.  
2. VENCLEXTA. Prescribing information. AbbVie Inc; 2020.

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Please see the US PI for full safety information regarding LDAC.

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## RAMP-UP DOSING

### Key point

- There is an initial dosing ramp-up schedule with VENCLYXTO for the treatment of AML over 3 or 4 days depending on the combination treatment the patient receives. After the ramp-up period, patients will remain on their recommended dose for the duration of their therapy<sup>1,2</sup>

### Adding context

- The dosing guidance provided is specific for AML and differs from chronic lymphocytic leukaemia (CLL) dosing. Please refer to the label for dosing instructions for other VENCLYXTO indications<sup>1,2</sup>
- In the treatment of AML, tumour lysis syndrome (TLS) has occurred in patients with high tumour burden when treated with VENCLYXTO<sup>1</sup>

### Suggestions to enhance the dialogue

- It is imperative that patients understand the ramp-up period for VENCLYXTO treatment and how it is used to prevent TLS, which is more likely to occur during the ramp-up period
- Patients should understand that adherence to dosing protocol is important

### Note

- Direct your patients to maintain hydration throughout the duration of treatment, especially before their first dose and on the day their dose is increased<sup>1</sup>

**REFERENCES:** 1. VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021. 2. VENCLEXTA. Prescribing information. AbbVie Inc; 2020.

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2. VENCLEXTA. Prescribing information. AbbVie Inc; 2020.

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### RECOMMENDED DOSING



Your **healthcare team will determine your recommended VENCLYXTO dose**. Once you have reached your recommended dose, you will continue treatment for as long as necessary. You will remain on treatment until your disease progresses.



Your **dosing schedule may be adjusted if you have side effects**, so it is important to talk to your healthcare team about any side effects you experience.



Your **dose may be adjusted if you take certain medicines**. Be sure to bring a list of any medicines you take, including vitamins and herbal supplements, with you to every doctor visit and update your healthcare team if you need to start taking a new medicine.

## RECOMMENDED DOSING

### Key point

- After the ramp-up dosing period, patients will remain on their recommended dose for the duration of their VENCLYXTO treatment

### Adding context

- Patients should continue to take VENCLYXTO treatment until disease progression or unacceptable toxicity is observed
- Some patients may require dosing schedule modifications or dose adjustments due to adverse events or concomitant medications during VENCLYXTO treatment

### Suggestions to enhance the dialogue

- Patients should know the dosing schedule for VENCLYXTO once they have completed ramp-up to their recommended dose
- Patients will benefit from a discussion emphasising the importance of communicating any AEs (adverse events) they experience, including TLS (tumour lysis syndrome), and any changes in concomitant medications, including over-the-counter medicines, since dose adjustments may be required

**REFERENCE:** VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021.

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## HOW TO TAKE IT



Take your VENCLYXTO dose at **around the same time every day with a meal**. During the first days or weeks of treatment as you slowly increase the dose, you should **take the tablets in the morning** to help you follow up with blood tests, if needed.



Swallow the tablets whole **with a glass of water**.



**Do not chew, crush, or break** the tablets.

### HOW TO TAKE IT (CONT'D)



You should **drink plenty of water** while taking VENCLYXTO. This is especially important when you are starting treatment and during any time there is a dose adjustment to help prevent an adverse event called tumour lysis syndrome.

Your doctor may also give you other medicines to reduce the uric acid in your blood before starting and during treatment with VENCLYXTO.

**NOTE:** It is very important that you stay well hydrated when taking VENCLYXTO, especially when you start treatment and increase your dose. Drinking water helps remove the breakdown of cancer cells from your blood through your urine.

## HOW TO TAKE IT

### Key point

- VENCLYXTO once-daily tablets are swallowed whole and taken around the same time each day with a glass of water and a meal

### Adding context

- It is important to monitor your patients' reactions to VENCLYXTO through blood tests. Blood tests should be assessed before they begin treatment, during the dose ramp-up period, and when they begin their full dose

### Suggestions to enhance the dialogue

- It is vital that patients know how they should take their VENCLYXTO tablets and also understand that adherence to dosing protocol is important
- Reiterate the importance of staying hydrated while on VENCLYXTO in order to help prevent TLS upon initiation and dose ramp-up

**REFERENCE:** VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021.

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## MISSED DOSE INSTRUCTIONS

If you missed your dose of VENCLYXTO:



By **less than 8 hours** from your scheduled daily time

- Take your missed dose as soon as possible
- Take your next dose the following day at your usual scheduled time



By **more than 8 hours** from your scheduled daily time

- Skip your missed dose
- Take your next dose the following day at your usual scheduled time



If you **vomit after** taking VENCLYXTO

- Do not take an extra dose that day. Take your next dose at the usual time the next day

## MISSED DOSE INSTRUCTIONS

### Key point

- Following the key administration steps can help ensure successful initiation and ongoing treatment on VENCLYXTO

### Suggestions to enhance the dialogue

- Patients should understand adherence to dosing protocol is important
- Encourage patients to consult their healthcare team if they have problems taking VENCLYXTO or questions about the use of this medicine

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### HOW YOUR TREATMENT WILL BE MONITORED



**During the ramp-up dosing phase, you will have regular blood tests** to monitor how your body is reacting to VENCLYXTO.



**Do not eat grapefruit products, Seville oranges** (bitter oranges), or **starfruit** (carambola) while you are taking VENCLYXTO. This also includes drinking the juice and taking a supplement that might contain them. This is because these products might affect the amount of VENCLYXTO in your blood.

## HOW YOUR TREATMENT WILL BE MONITORED

### Key point

- It is recommended to monitor your patients closely during treatment with VENCLYXTO

### Adding context

- It is important to monitor your patients' reactions to VENCLYXTO through blood tests. Blood tests should be assessed before they begin treatment, during the dose ramp-up period, and when they begin their full dose

### Suggestions to enhance the dialogue

- Communicate with patients the types of foods to avoid while on therapy

**REFERENCE:** VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021.

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### TESTS AND ASSESSMENTS



Be sure to **keep all of your appointments** for tests.



These tests will help your doctor **monitor your blood chemistry closely** to determine if your therapy is working and if you are experiencing any side effects that may need to be addressed.

A bone marrow assessment is recommended after your first cycle of treatment to evaluate your level of remission, which will help your doctor manage any side effects you experience.

## TESTS AND ASSESSMENTS

### Key point

- Regular blood tests and additional assessments are needed to evaluate the efficacy and safety of VENCLYXTO therapy

### Adding context

- TLS prophylaxis and monitoring measures should be followed prior to initiation and during ramp-up. Additional measures for patients with TLS risk factors are needed (refer to the SmPC for more information)
- Before starting treatment and during ongoing dosing, blood tests monitor for cytopenia and other adverse events
- A bone marrow assessment is recommended to evaluate treatment response, including remissions and AEs
- In clinical trials, a majority of patients experienced a treatment response early in therapy
- In a number of patients, therapeutic responses were observed after Cycle 2

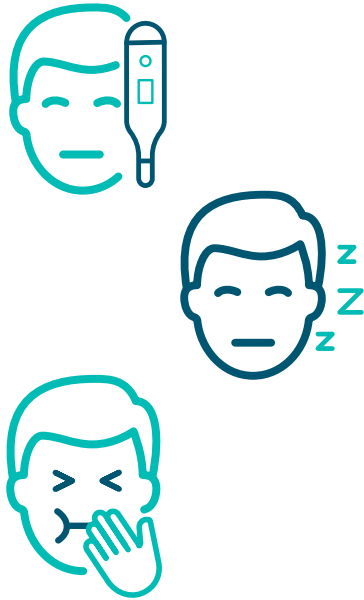
### Suggestions to enhance the dialogue

- It is important that patients understand why they should keep scheduled appointments for blood work or other assessments
- Ensure patients understand that each patient can respond differently to treatment. Some patients may potentially respond as early as Cycle 1, while others may respond after Cycle 2 of treatment

**REFERENCE:** VENCLYXTO Summary of Product Characteristics. Ludwigshafen, Germany: AbbVie Deutschland GmbH & Co. KG. 2021.

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### POSSIBLE SIDE EFFECTS



#### Tell your doctor about any side effects you experience with VENCLYXTO

Very common side effects that may affect more than 1 in 10 people taking VENCLYXTO include low white blood cell count and infections. Low white blood cell count can increase your risk for infection. Signs of low white blood cell count may include fever, chills, feeling weak or confused, cough, pain or burning feeling when passing urine. Please refer to the package leaflet for the full list of potential side effects.

Stop taking VENCLYXTO and seek medical attention immediately if you notice any symptoms of tumour lysis syndrome, including:

- Fever
- Chills
- Nausea
- Vomiting
- Confusion
- Shortness of breath
- Seizure
- Irregular heartbeat
- Dark or cloudy urine
- Unusual tiredness
- Muscle pain
- Abdominal pain and distention
- Joint discomfort

To manage your side effects, your doctor may adjust your dose. You may also need to receive intravenous fluids into your veins.

## POSSIBLE SIDE EFFECTS

### Key point

- Patients should report any signs of potential AEs to you so you can help manage them

### Adding context

- The most common adverse events experienced by patients with AML in clinical trials included pneumonia, sepsis, urinary tract infection, neutropaenia, febrile neutropaenia, anaemia, thrombocytopaenia, hypokalaemia, decreased appetite, tumour lysis syndrome, dizziness/syncope, headache, hypotension, haemorrhage, dyspnoea, nausea, diarrhoea, vomiting, stomatitis, abdominal pain, cholecystitis/cholelithiasis, arthralgia, fatigue, asthenia, weight decreased, and blood bilirubin increased

### Suggestions to enhance the dialogue

- Patients may like to know what to expect when it comes to the AEs they may experience with VENCLYXTO
- Reiterate the importance of staying hydrated while on VENCLYXTO therapy to help prevent TLS upon initiation and dose ramp-up

### Note

- Direct your patients to maintain hydration throughout the duration of treatment, especially before their first dose and on the day their dose is increased

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### DO'S OF TAKING VENCLYXTO



**DO** tell your healthcare team about all of the medicines you take, including prescriptions, over-the-counter medicines, vitamins, and herbal supplements



**DO** take VENCLYXTO exactly as your doctor prescribes it



**DO** swallow VENCLYXTO tablets whole



**DO** take VENCLYXTO 1 time a day with a meal and water at about the same time each day



**DO** talk to your doctor about any side effects you experience



**DO** drink plenty of water every day



**DO** keep this medicine away from children



**DO** read the package leaflet carefully and keep it to reference if needed

### DON'TS OF TAKING VENCLYXTO



**DO NOT** change your dose or stop taking VENCLYXTO unless your doctor tells you to



**DO NOT** chew, crush, or break the tablets



**DO NOT** drink grapefruit juice or eat grapefruit, Seville oranges (often used in marmalades), or starfruit (carambola) while you are taking VENCLYXTO



**DO NOT** use VENCLYXTO after its expiry date



**DO NOT** take an extra dose of VENCLYXTO if you vomit after taking it

## DO'S AND DON'TS OF TAKING VENCLYXTO

### Key point

- It is important that patients adhere to the do's and don'ts of VENCLYXTO therapy

### Suggestions to enhance the dialogue

- Ensure your patients understand that following appropriate treatment guidelines may help them successfully initiate and continue treatment with VENCLYXTO
- Discuss with patients the importance of communicating any AEs, including TLS, and concomitant medications, including over-the-counter medications, since dose adjustment may be required

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