

VENCLEXTA is a prescription medicine used in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, **or** have other medical conditions that prevent the use of standard chemotherapy. It is not known if VENCLEXTA is safe and effective in children.

VENCLEXTA + azacitidine **PROVEN TO HELP**

SOME ADULTS WITH **NEWLY DIAGNOSED AML LIVE LONGER**

It is not known if VENCLEXTA is safe and effective in children.

Actor portrayal.

Half of patients treated with VENCLEXTA + azacitidine were still alive at 15 months vs 10 months for those receiving treatment with azacitidine alone.

In a clinical study of 431 adults with newly diagnosed acute myeloid leukemia (AML), who were 75 years of age or older, or had other medical conditions that prevented the use of standard chemotherapy, 286 patients received VENCLEXTA + azacitidine and 145 patients received azacitidine + placebo (an inactive medication), also considered as azacitidine alone.

Important Safety Information

What is the most important information I should know about VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

Tumor lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests to check your risk of getting TLS before you start taking VENCLEXTA. You will receive other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS. You may also need to receive intravenous (IV) fluids into your vein. Your healthcare provider will do blood tests to check for TLS when you first start treatment and during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain.

Please see additional Important Safety Information on pages 28 to 29. Please see full Prescribing Information, including Medication Guide, at www.rxabbvie.com/pdf/venclexta.pdf.

GET STARTED >

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HOW TO START WITH A VENCLEXTA BASED REGIMEN



This brochure was developed to help you, your family, and your caregivers better understand your diagnosis and what to expect throughout treatment if you and your doctor choose a VENCLEXTA-based regimen.



Remember, always discuss any questions you may have about VENCLEXTA with your healthcare team members-they are there to guide you.

Please see Important Safety Information on pages 28 to 29. Please see full Prescribing Information, including Medication Guide, at www.rxabbvie.com/pdf/venclexta.pdf.









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To return to the Front





UNDERSTANDING AML (ACUTE MYELOID LEUKEMIA)



AML is a complex disease, but with the right information you can help the people in your life better understand your diagnosis and its impact.

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What is AML?

AML is a type of blood cancer that starts in your bone marrow. Normally, healthy bone marrow is filled with red blood cells, white blood cells, and platelets.

When you have AML, cancer cells don't die when they should. Instead, they multiply to build up in your bone marrow and eventually crowd out these normal healthy cells.



General symptoms of AML

Symptoms of AML are often general and nonspecific, and can include:



It's important to remember that these symptoms may be the result of health-related conditions unrelated to AML. If you are experiencing any of these symptoms, especially for an extended period of time, it's important to see a doctor to be properly treated.

In addition, the crowding out of healthy blood cells in diagnosed AML can lead to:

Anemia

A condition in which you don't have enough healthy red blood cells to carry sufficient oxygen to the body's tissues.

Symptoms can include fatigue or weakness.

Neutropenia

A condition where you have too few neutrophils, a type of white blood cell that is important for fighting bacterial infections.

A common symptom is increased likelihood of infections.

Thrombocytopenia

A condition in which you have a low blood platelet count (platelets are cells in your blood that help your body form clots to stop bleeding).

Symptoms can include bruising or excess bleeding.

If you are experiencing any of these symptoms, especially for an extended period of time, it's important to let your doctor know.

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Risk factors

Risk factors for AML can include:



Diagnosis information

The time between diagnosis and the beginning of treatment can often be brief. After diagnosis, your healthcare provider will perform a series of tests-known as a "workup." These may include:



Treatment for AML varies and is often unique to the individual. Your healthcare provider will recommend treatment based on the results of your workup and your preferences as a patient.

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TREATMENT OPTIONS



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What are some of the common treatments for AML?

AML can be treated with the help of cancer-fighting medicines, like VENCLEXTA (ven-KLEKS-tuh). Other common treatments for AML include:



Targeted therapy: These treatments "target" a specific protein, mutation, or receptor in the body and can include certain types of inhibitors.



Hypomethylating agents: Generally reserved for those who are older or who have other health conditions, these agents help restore the normal function of genes that suppress the formation of tumors.



Chemotherapy: This treatment uses powerful chemicals to kill fast-growing cells in your body, including cancer cells. Standard chemotherapy can be given at a high or low dose, depending on the aggressiveness of the cancer and the patient's ability to tolerate it based on other health factors.



Radiation therapy: Only used for specific cases of AML, this treatment uses radiation to kill cancer cells and

noncancerous cells or slow their growth by damaging their DNA. Cancer cells with DNA that are damaged beyond repair either stop dividing or die.



Stem cell transplant: This procedure transfers stem cells from a healthy donor to the patient or can be done using the patient's own stem cells (autologous transplant). If successful, it can replace stem cells in the bone marrow. This procedure involves chemotherapy and possibly radiation to prepare the body.



Supportive care: (This is not a treatment for AML.)

This involves the management of symptoms related to the disease or therapy and can range from services that help with cancer pain and fatigue to palliative care and distress management.

Let's learn more about AML treatment with a VENCLEXTA-based regimen.

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HOW DOES VENCLEXTA WORK AGAINST AML?



What is VENCLEXTA?

VENCLEXTA is a prescription medicine used in combination with azacitidine, or decitabine, or low-dose cytarabine to treat adults with newly diagnosed acute myeloid leukemia (AML) who:

- are 75 years of age or older, or
- have other medical conditions that prevent the use of standard chemotherapy.

It is not known if VENCLEXTA is safe and effective in children.

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Remember, always discuss any questions you may have about VENCLEXTA with your healthcare team members—they are there to guide you.



How does VENCLEXTA work against AML?

VENCLEXTA is a pill that works differently than other treatments. It binds to a specific protein in your body called BCL-2 (B-cell lymphoma 2). This helps restore what is called apoptosis, a process of natural cell death that is disrupted when you have cancer, restoring the body's natural ability to tell cancer cells to die.

Once this process is restored, your body can begin to kill cancer cells. With fewer cancer cells, there is now room for healthy cells to grow in the bone marrow.



Let's learn more about AML treatment with a **VENCLEXTA-based regimen.**

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THIS SECTION IS DESIGNED TO HELP YOU LEARN ABOUT TREATING **1LAMLWITHVENCLEXTA+** AZACITIDINE



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In a clinical study, VENCLEXTA + azacitidine was found to help some adults with newly diagnosed AML live longer than those treated with azacitidine alone

VENCLEXTA + azacitidine was studied in 431 adults with newly diagnosed acute myeloid leukemia (AML) who were age 75 years or older, or who had other medical conditions that prevented the use of standard chemotherapy. In the study, 286 patients received VENCLEXTA + azacitidine and 145 patients received azacitidine + placebo (an inactive medication), also considered as azacitidine alone.

Half of patients treated with VENCLEXTA + azacitidine were still alive at 15 months vs 10 months for those receiving treatment with azacitidine alone.

Median overall survival (OS)*

Half of patients were still alive at:



VENCLEXTA may not work for everyone.

*Median overall survival (OS)=the length of time from the start of treatment in a clinical trial that half of the patients are still alive.



The study showed that there was a

REDUCTION in the risk of death in patients treated with VENCLEXTA + azacitidine

compared with those treated with azacitidine alone.

VENCLEXTA may not work for everyone.

Important Safety Information

What is the most important information I should know about VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

Tumor lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests to check your risk of getting TLS before you start taking VENCLEXTA. You will receive other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS. You may also need to receive intravenous (IV) fluids into your vein. Your healthcare provider will do blood tests to check for TLS when you first start treatment and during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain.









To determine if treatment is working, your doctor may run some tests after starting your treatment to see if you have a decrease in or disappearance of signs of cancer, meaning you have achieved remission.

Remission and the level of remission achieved will vary from patient to patient and from treatment to treatment.



There are different kinds of remission

When there is complete remission (CR), blood counts are normal, fewer than 5% of bone marrow cells are leukemia cells, and no signs of cancer are seen elsewhere in the body:

- Patients do not need to receive red blood cell transfusions
- Patients may not need to receive platelet transfusions based on their platelet levels and no signs of bleeding

When there is CRh, or complete remission with partial hematologic recovery, no signs of cancer are seen, but some blood counts have not returned to normal levels.

Important Safety Information

What is the most important information I should know about VENCLEXTA? (cont'd)

Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting TLS. Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of VENCLEXTA, and each time your dose is increased.

Your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects. When restarting VENCLEXTA after stopping for 1 week or longer, your healthcare provider may again check for your risk of TLS and change your dose.

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Remission may be possible with VENCLEXTA + azacitidine

More patients treated with VENCLEXTA + azacitidine achieved remissions than with azacitidine alone.

Combined complete remission (CR) and complete remission with partial hematologic recovery (CRh) was 65%

VEN+AZA



When treated with VENCLEXTA + azacitidine

- 37% (105 of 286 people) achieved complete remission (CR) when treated with VENCLEXTA + azacitidine
- 28% (80 of 286 people) achieved complete remission with partial hematologic recovery (CRh) when treated with VENCLEXTA + azacitidine
- 65% (185 of 286 people) achieved complete remission (CR) or complete remission with partial hematologic recovery (CRh) when treated with VENCLEXTA + azacitidine

VENCLEXTA may not work for everyone.

compared with

Combined complete remission (CR) and complete remission with partial hematologic recovery (CRh) was 23%

PBO+AZA 100% Percentage of patients (%)

When treated with azacitidine alone

- 18% (26 of 145 people) achieved complete remission (CR) when treated with azacitidine alone
- 5% (7 of 145 people) achieved complete remission with • partial hematologic recovery (CRh) when treated with azacitidine alone
- 23% (33 of 145 people) achieved complete remission (CR) or complete remission with partial hematologic recovery (CRh)



CRh

CR+CRh

when treated with azacitidine alone

How long may remission last with VENCLEXTA + azacitidine?

During this study, of the patients who achieved some level of remission, either complete remission (CR) or complete remission with partial hematologic recovery (CRh), the median length of time spent in:

- complete remission (CR) was 18 months for patients treated with VENCLEXTA + azacitidine compared with 13 months for patients treated with azacitidine alone
- complete remission (CR) + complete remission with partial hematologic recovery (CRh) was 18 months for patients treated with VENCLEXTA + azacitidine compared with 14 months for patients treated with azacitidine alone

L What is remission?

Remission means a decrease in or disappearance of signs and symptoms of cancer.

CR, or complete remission, means the blood count is normal, fewer than 5% of bone marrow cells are leukemia cells, and no signs of cancer are seen elsewhere in the body.

CRh, or complete remission with partial hematologic recovery, means that no signs of cancer are seen, but some blood counts have not returned to normal levels.

See Section There are different kinds of remission on page 13 for more information.

What does "median" mean?

Median means the middle number in a group of numbers that are arranged from lowest to highest. For example, in the group of numbers 1 to 13, 7 is the median.

Important Safety Information

Who should not take VENCLEXTA?

Certain medicines must not be taken when you first start taking VENCLEXTA and while your dose is being slowly increased because of the risk of increased TLS.

- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects.
- Do not start new medicines during treatment with VENCLEXTA without first talking with your healthcare provider.

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How long before patients see a treatment response with VENCLEXTA + azacitidine?

Half of all patients who achieved some level of remission, either complete remission (CR) or complete remission with partial hematologic recovery (CRh), did so in 1 month.



Remissions with VENCLEXTA + azacitidine were achieved as early as 0.6 month to as late as 14.3 months after starting treatment.

Remember, individual results with VENCLEXTA may vary.

The time it takes to work and how long the effects last vary from person to person.

What is remission?

Remission means a decrease in or disappearance of signs and symptoms of cancer.

CR, or complete remission, means the blood count is normal, fewer than 5% of bone marrow cells are

leukemia cells, and no signs of cancer are seen elsewhere in the body.

CRh, or complete remission with partial hematologic recovery, means that no signs of cancer are seen, but some blood counts have not returned to normal levels.

See Section There are different kinds of remission on page 13 for more information.

What does "median" mean?

Median means the middle number in a group of numbers that are arranged from lowest to highest. For example, in the group of numbers 1 to 13, 7 is the median.

Important Safety Information

Who should not take VENCLEXTA? (cont'd)

Before taking VENCLEXTA, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney or liver problems.
- have problems with your body salts or electrolytes, such as potassium, phosphorus, or calcium.
- have a history of high uric acid levels in your blood or gout.
- are scheduled to receive a vaccine. You should not receive a "live vaccine" before, during, or after treatment with VENCLEXTA, until your healthcare provider tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your healthcare provider. These vaccines may not be safe or may not work as well during treatment with VENCLEXTA.
- are pregnant or plan to become pregnant. VENCLEXTA may harm your unborn baby. If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with VENCLEXTA, and you should use effective birth control during treatment and for 30 days after the last dose of VENCLEXTA. If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if VENCLEXTA passes into your breast milk. Do not breastfeed during treatment with VENCLEXTA and for 1 week after last dose.

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THIS SECTION IS DESIGNED TO HELP YOU LEARN ABOUT TREATING AML WITH VENCLEXTA + DECITABINE



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To determine if treatment is working, your doctor may run some tests after starting your treatment to see if you have a decrease in or disappearance of signs of cancer, meaning you have achieved remission.

Remission and the level of remission achieved will vary from patient to patient and from treatment to treatment.



There are different kinds of remission

When there is complete remission (CR), blood counts are normal, fewer than 5% of bone marrow cells are leukemia cells, and no signs of cancer are seen elsewhere in the body:

- Patients do not need to receive red blood cell transfusions
- Patients may not need to receive platelet transfusions based on their platelet levels and no signs of bleeding

When there is CRh, or complete remission with partial hematologic recovery, no signs of cancer are seen, but some blood counts have not returned to normal levels.

Important Safety Information

What is the most important information I should know about VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

Tumor lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests to check your risk of getting TLS before you start taking VENCLEXTA. You will receive other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS. You may also need to receive intravenous (IV) fluids into your vein. Your healthcare provider will do blood tests to check for TLS when you first start treatment and during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain.

Please see additional Important Safety Information on pages 28 to 29. Please see full Prescribing Information, including Medication Guide, at www.rxabbvie.com/pdf/venclexta.pdf.









Remission may be possible with VENCLEXTA + decitabine

VENCLEXTA + decitabine was studied in 13 adults with newly diagnosed AML who were age 75 or older or had other medical conditions that prevented the use of standard chemotherapy. The clinical study did not include patients on decitabine alone.

Combined complete remission (CR) and complete remission with partial hematologic recovery (CRh) was 62%



When treated with VENCLEXTA + decitabine

- 54% (7 of 13 people) achieved complete remission (CR) when treated with VENCLEXTA + decitabine
- 8% (1 of 13 people) achieved complete remission with partial hematologic recovery (CRh) when treated with VENCLEXTA + decitabine
- 62% (8 of 13 people) achieved complete remission (CR) or complete remission with partial hematologic recovery (CRh) when treated with VENCLEXTA + decitabine

VENCLEXTA may not work for everyone.

How long may remission last with VENCLEXTA + decitabine?

Patients in the study were followed for a median of 11 months, with a range of 0.7 month to up to 38.8 months. The median length of time spent in complete remission (CR) was 13 months and in complete remission (CR) + complete remission with partial hematologic recovery (CRh) was also 13 months.

What is remission?

Remission means a decrease in or disappearance of signs and symptoms of cancer.

CR, or complete remission, means the blood count is normal, fewer than 5% of bone marrow cells are leukemia cells, and no signs of cancer are seen elsewhere in the body.

CRh, or complete remission with partial hematologic recovery, means that no signs of cancer are seen, but some blood counts have not returned to normal levels.

See Section *There are different kinds of remission* on page 17 for more information.

M What does "median" mean?

Median means the middle number in a group of numbers that are arranged from lowest to highest. For example, in the group of numbers 1 to 13, 7 is the median.

Important Safety Information

What is the most important information I should know about VENCLEXTA? (cont'd)

Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting TLS. Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of VENCLEXTA, and each time your dose is increased.

Your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects. When restarting VENCLEXTA after stopping for 1 week or longer, your healthcare provider may again check for your risk of TLS and change your dose.

Please see additional Important Safety Information on pages 28 to 29. Please see full Prescribing Information, including Medication Guide, at www.rxabbvie.com/pdf/venclexta.pdf.







How long before patients see a treatment response with VENCLEXTA + decitabine?

Half of all patients who achieved some level of remission, either complete remission (CR) or complete remission with partial hematologic recovery (CRh), did so in 2 months.



Remissions with VENCLEXTA + decitabine

were achieved from as early as 0.8 month to as late as 4.2 months after starting treatment.

Remember, individual results with VENCLEXTA may vary.

The time it takes to work and how long the effects last vary from person to person.

M What is remission?

Remission means a decrease in or disappearance of signs and symptoms of cancer.

CR, or complete remission, means the blood count is normal, fewer than 5% of bone marrow cells are leukemia cells, and no signs of cancer are seen elsewhere in the body.

CRh, or complete remission with partial hematologic recovery, means that no signs of cancer are seen, but some blood counts have not returned to normal levels.

See Section *There are different kinds of remission* on page 17 for more information.

Important Safety Information

Who should not take VENCLEXTA?

Certain medicines must not be taken when you first start taking VENCLEXTA and while your dose is being slowly increased because of the risk of increased TLS.

- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects.
- Do not start new medicines during treatment with VENCLEXTA without first talking with your healthcare provider.

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VENCLEXTA + Low-dose cytarabine

THIS SECTION IS DESIGNED TO HELP YOU LEARN ABOUT TREATING AML WITH VENCLEXTA + LOW-DOSE CYTARABINE











VENCLEXTA + Low-dose cytarabine

To determine if treatment is working, your doctor may run some tests after starting your treatment to see if you have a decrease in or disappearance of signs of cancer, meaning you have achieved remission.

Remission and the level of remission achieved will vary from patient to patient and from treatment to treatment.



There are different kinds of remission

When there is complete remission (CR), blood counts are normal, fewer than 5% of bone marrow cells are leukemia cells, and no signs of cancer are seen elsewhere in the body:

- Patients do not need to receive red blood cell transfusions
- Patients may not need to receive platelet transfusions based on their platelet levels and no signs of bleeding

When there is CRh, or complete remission with partial hematologic recovery, no signs of cancer are seen, but some blood counts have not returned to normal levels.

Important Safety Information

What is the most important information I should know about VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

Tumor lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests to check your risk of getting TLS before you start taking VENCLEXTA. You will receive other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS. You may also need to receive intravenous (IV) fluids into your vein. Your healthcare provider will do blood tests to check for TLS when you first start treatment and during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain.

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VENCLEXTA + Low-dose cytarabine

Remission may be possible with VENCLEXTA + low-dose cytarabine (LDAC)

VENCLEXTA + LDAC was studied in 211 adults with newly diagnosed AML who were age 75 years or older, or who had other medical conditions that prevented the use of standard chemotherapy. In the study, 143 patients received VENCLEXTA + LDAC and 68 patients received LDAC + placebo (an inactive medication), also considered as LDAC alone.

Percentage of patients who achieved complete remission (CR) and the median length of time spent in CR:

- For patients treated with VENCLEXTA + LDAC, 27% of 143 patients achieved CR and the median length of time spent in CR was 11 months
- For patients treated with LDAC alone, 7% of 68 patients achieved CR and the median length of time spent in CR was 8 months
- For patients treated with VENCLEXTA + LDAC, half of those who achieved complete remission (CR) or complete remission with partial hematologic recovery (CRh) did so in 1 month. Remissions were achieved as early as 0.7 month and as late as 5.8 months
- VENCLEXTA + LDAC did not significantly reduce the risk of death compared to patients receiving LDAC alone

Ш What is remission?

Remission means a decrease in or disappearance of signs and symptoms of cancer.

CR, or complete remission, means the blood count is normal, fewer than 5% of bone marrow cells are

leukemia cells, and no signs of cancer are seen elsewhere in the body.

CRh, or complete remission with partial hematologic recovery, means that no signs of cancer are seen, but some blood counts have not returned to normal levels.

Ш What does "median" mean?

Median means the middle number in a group of numbers that are arranged from lowest to highest. For example, in the group of numbers 1 to 13, 7 is the median.

Important Safety Information

What is the most important information I should know about VENCLEXTA? (cont'd)

Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting TLS. Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of VENCLEXTA, and each time your dose is increased.

Your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects. When restarting VENCLEXTA after stopping for 1 week or longer, your healthcare provider may again check for your risk of TLS and change your dose.

Who should not take VENCLEXTA?

Certain medicines must not be taken when you first start taking VENCLEXTA and while your dose is being slowly increased because of the risk of increased TLS.

- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects.
- Do not start new medicines during treatment with VENCLEXTA without first talking with your healthcare provider.









STARTING TREATMENT WITH VENCLEXTA



If you and your doctor decide to treat your AML with a VENCLEXTA-combination regimen, here's what you need to know and do before you start taking VENCLEXTA.











Before starting treatment with VENCLEXTA-based therapy



Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements



Before taking VENCLEXTA, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have liver problems
- have problems with your body salts or electrolytes, such as potassium, phosphorus, or calcium
- have a history of high uric acid levels in your blood or gout
- are scheduled to receive a vaccine. You should not receive a "live vaccine" before, during, or after treatment with VENCLEXTA, until your healthcare provider tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your healthcare provider. These vaccines may not be safe or may not work as well during treatment with VENCLEXTA

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Review instructions for taking VENCLEXTA with your healthcare provider

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Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose to reduce the risk of TLS (read more about TLS below)

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How should I take VENCLEXTA?

Take VENCLEXTA exactly as your healthcare provider tells you to take it. Do not change your dose of VENCLEXTA or stop taking VENCLEXTA unless your healthcare provider tells you to.

When you first take VENCLEXTA:

- You may need to take VENCLEXTA at a hospital or clinic to be monitored for TLS.
- Your healthcare provider will start VENCLEXTA at a low dose. Your dose will be slowly increased daily up to the full dose. Follow your healthcare provider's instructions carefully while increasing to the full dose.
- Take VENCLEXTA 1 time a day with a meal and water at about the same time each day.
- Swallow VENCLEXTA tablets whole. Do not chew, crush, or break the tablets.
- Keep VENCLEXTA in original packaging to protect from moisture.
- If you miss a dose of VENCLEXTA and it has been less than 8 hours, take your dose as soon as possible. If you miss a dose of VENCLEXTA and it has been more than 8 hours, skip the missed dose and take the next dose at your usual time.
- If you vomit after taking VENCLEXTA, do not take an extra dose. Take the next dose at your usual time the next day.

What is important information I should know about taking **VENCLEXTA?**



Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting TLS.

Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of VENCLEXTA, and each time your dose is increased.



Your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects.









Getting started: Starting treatment with VENCLEXTA-based therapy



When you first take VENCLEXTA, you may need to take VENCLEXTA at a hospital or clinic to be monitored for tumor lysis syndrome (TLS; see page 30 for the definition of TLS)



 \checkmark

Your healthcare team will start you on a low dose of VENCLEXTA and increase it daily up to your full dose as shown on page 27

During treatment with VENCLEXTA-based therapy

DO

- Take VENCLEXTA exactly as your healthcare provider tells you to take it \checkmark
 - When you first take VENCLEXTA:
 - You may need to take VENCLEXTA at a hospital or clinic to be monitored for TLS.
 - Your healthcare provider will start VENCLEXTA at a low dose and slowly increase it daily up to the full dose. Follow your healthcare provider's instructions carefully while increasing to the full dose
- Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting TLS
 - Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of VENCLEXTA, and each time your dose is increased
- Be aware that your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if side effects occur
- Be aware that when restarting VENCLEXTA after stopping for 1 week \checkmark or longer, your healthcare provider may again check for your risk of TLS (see definition of TLS on page 30) and change your dose
- Take VENCLEXTA 1 time a day with a meal and water, at about the same \checkmark time each day
- Swallow VENCLEXTA tablets whole. Do not chew, crush, or break the tablets
- Keep VENCLEXTA in original packaging to protect from moisture \checkmark
- If you miss a dose of VENCLEXTA and it has been less than 8 hours, take your \checkmark dose as soon as possible
 - If you miss a dose of VENCLEXTA and it has been more than 8 hours, skip the missed dose and take the next dose at your usual time
- Tell your healthcare provider about all the medicines you take, including \checkmark prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects

DON'T

- Don't change your dose of VENCLEXTA or stop taking VENCLEXTA \mathbf{X} unless your healthcare provider tells you to
- Don't crush, chew, or break the tablets (\mathbf{X})
- \mathbf{X} Don't transfer tablets to a different container
- Don't take an extra dose if you vomit after taking VENCLEXTA. Instead, \mathbf{X} take the next dose at your scheduled time the next day
- Don't drink grapefruit juice or eat grapefruit, Seville oranges (often used \mathbf{X} in marmalades), or starfruit while you are taking VENCLEXTA. These products may increase the amount of VENCLEXTA in your blood
- Don't start new medicines during treatment with VENCLEXTA without first \mathbf{X} talking with your healthcare provider



Drink plenty of water every day when taking VENCLEXTA to help reduce your risk of a potential side effect called tumor lysis syndrome, or TLS.









VENCLEXTA ORAL DOSING SCHEDULE*

Day

VENCLEXTA once daily

1	Take 100 mg of VENCLEXTA and your healthcare provider will start you on azacitidine 75 mg/m ² (IV or SC), or decitabine 20 mg/m ² (IV), or cytarabine 20 mg/m ² (SC) as determined by your healthcare provider.	100 mg	100
2	Take 200 mg of VENCLEXTA in combination with azacitidine 75 mg/m ² (IV or SC), or decitabine 20 mg/m ² (IV), or cytarabine 20 mg/m ² (SC) as determined by your healthcare provider.	200 mg	100 100
3	Take 400 mg of VENCLEXTA in combination with azacitidine 75 mg/m ² (IV or SC), or decitabine 20 mg/m ² (IV), or cytarabine 20 mg/m ² (SC) as determined by your healthcare provider.	400 mg	100 100 100 100

Day 4 and beyond (28-day cycle)

In combination with azacitidine or decitabine: Take 400 mg of VENCLEXTA in combination



For illustrative purposes only; pills are not actual size.

*Dosing may differ depending on other types of medications you may be taking.

The recommended dose of VENCLEXTA may be delivered using any of the approved tablet strengths (e.g., patients can take 2 x 50 mg tablets or 10 x 10 mg tablets instead of 1 x 100 mg tablet as needed).

Intravenous (IV) means within a vein. In this type of injection, the medication is injected directly into the vein.

Subcutaneous (SC) means under the skin. In this type of injection, the medication is injected into the tissue layer between the skin and the muscle.

> Your doctor may delay, decrease, or stop treatment for a period of time based on your lab work. This is common in treatment management. Be sure to ask your doctor if you have any questions about changes in dosing.











IMPORTANT SAFETY INFORMATION

What is the most important information I should know about VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

Tumor lysis syndrome (TLS). TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure, the need for dialysis treatment, and may lead to death. Your healthcare provider will do tests to check your risk of getting TLS before you start taking VENCLEXTA. You will receive other medicines before starting and during treatment with VENCLEXTA to help reduce your risk of TLS. You may also need to receive intravenous (IV) fluids into your vein. Your healthcare provider will do blood tests to check for TLS when you first start treatment and during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including fever, chills, nausea, vomiting, confusion, shortness of breath, seizures, irregular heartbeat, dark or cloudy urine, unusual tiredness, or muscle or joint pain.

Drink plenty of water during treatment with VENCLEXTA to help reduce your risk of getting TLS. Drink 6 to 8 glasses (about 56 ounces total) of water each day, starting 2 days before your first dose, on the day of your first dose of VENCLEXTA, and each time your dose is increased.

Your healthcare provider may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects. When restarting VENCLEXTA after stopping for 1 week or longer, your healthcare provider may again check for your risk of TLS and change your dose.

Who should not take VENCLEXTA?

Certain medicines must not be taken when you first start taking VENCLEXTA and while your dose is being slowly increased because of the risk of increased TLS.

- Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VENCLEXTA and other medicines may affect each other, causing serious side effects.
- Do not start new medicines during treatment with VENCLEXTA without first talking with your healthcare provider.

Before taking VENCLEXTA, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney or liver problems.
- have problems with your body salts or electrolytes, such as potassium, phosphorus, or calcium.
- have a history of high uric acid levels in your blood or gout.
- are scheduled to receive a vaccine. You should not receive a "live vaccine" before, during, or after treatment with VENCLEXTA, until your healthcare provider tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your healthcare provider. These vaccines may not be safe or may not work as well during treatment with VENCLEXTA.









Before taking VENCLEXTA, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

- are pregnant or plan to become pregnant. VENCLEXTA may harm your unborn baby. If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with VENCLEXTA, and you should use effective birth control during treatment and for 30 days after the last dose of VENCLEXTA. If you become pregnant or think you are pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if VENCLEXTA passes into your breast milk. Do not breastfeed during treatment with VENCLEXTA and for 1 week after last dose.

What should I avoid while taking VENCLEXTA?

You should not drink grapefruit juice or eat grapefruit, Seville oranges (often used in marmalades), or starfruit while you are taking VENCLEXTA. These products may increase the amount of VENCLEXTA in your blood.

What are the possible side effects of VENCLEXTA?

VENCLEXTA can cause serious side effects, including:

- Low white blood cell counts (neutropenia). Low white blood cell counts are common with VENCLEXTA, but can also be severe. Your healthcare provider will do blood tests to check your blood counts during treatment with VENCLEXTA and may pause dosing.
- Infections. Death and serious infections such as pneumonia and blood infection (sepsis) have happened during treatment with VENCLEXTA. Your healthcare provider will closely monitor and treat you right away if you have a fever or any signs of infection during treatment with VENCLEXTA.

Tell your healthcare provider right away if you have a fever or any signs of an infection during treatment with VENCLEXTA.

The most common side effects of VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine in people with AML include nausea; diarrhea; low platelet count; constipation; low white blood cell count; fever with low white blood cell count; tiredness; vomiting; swelling of arms, legs, hands, or feet; fever; infection in lungs; shortness of breath; bleeding; low red blood cell count; rash; stomach (abdominal) pain; infection in your blood; muscle and joint pain; dizziness; cough; sore throat; and low blood pressure.

VENCLEXTA may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of VENCLEXTA. Call your doctor for medical advice about side effects.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you cannot afford your medication, contact www.genentech-access.com/patient/ brands/venclexta for assistance.

> Notify your doctor or healthcare team *immediately* if you experience any of these symptoms.

Read the next few pages for more signs and symptoms to look out for.









SIDE EFFECTS

What is TLS, or tumor lysis syndrome?

TLS, or tumor lysis syndrome, is caused when cancer cells break down too fast. This can cause kidney failure, the need for dialysis treatment, and may lead to death.

Your healthcare provider will do tests for TLS, so keeping appointments for those tests is important.

To help reduce TLS risk, you will receive other medicines before starting and during treatment with VENCLEXTA. You may also need to receive intravenous fluids into your vein.

Tell your healthcare provider right away if you have any symptoms of TLS during treatment with VENCLEXTA, including:

- fever
- chills
- nausea
- vomiting

- confusion
- shortness of breath
- seizures
- irregular heartbeat
- dark or cloudy urine
- unusual tiredness
- muscle or joint pain

Your healthcare provider may delay or decrease your dose or stop treatment if you have side effects. Don't stop or change your dose unless directed by your healthcare provider. VENCLEXTA may cause fertility problems in men. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of VENCLEXTA. Call your healthcare provider for medical advice about side effects.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.











Management of neutropenia and infections: Help your doctor help you

Talk to your doctor about **neutropenia**, the most common side effect of both AML and VENCLEXTA-based regimens.

You may experience neutropenia at any point during your AML treatment, but together, you and your doctor can help manage this common condition.

What is neutropenia?

Neutropenia is a condition that happens when levels of a type of white blood cell, neutrophils, drop. Normally, this type of white blood cell is important to help control infections in the body.

Neutropenia puts you at risk for serious, or even fatal, infections.

Neutropenia is a serious condition caused by both AML and treatment for AML. This common condition can occur before beginning AML treatment or at any point during AML treatment, so it is important to monitor for any of the symptoms below during the entire course of your treatment.

How do I know if I have neutropenia or an infection?

Symptoms of neutropenia or infections include:

- fever
- chills
- neck pain/stiff neck
- mouth sores or sore throat
- cough

- confusion/"seeming different"
- difficulty breathing
- abdominal or rectal pain
- pain or burning with urination

Notify your doctor or healthcare team immediately if you experience any of these symptoms.











Neutropenia: Lowering your risk for developing infections

Since neutropenia places you at high risk for developing infections, preventing infections is extremely important. While your doctor is there to help manage your side effects, there are steps you can take to help minimize the risk of infection during treatment with a VENCLEXTA-based regimen.

What you can do to lower your infection risk:

DO

- Wash your hands with soap and water frequently, especially before eating and after trips to the bathroom, coughing or sneezing, touching surfaces in public, touching pets, and disposing of trash
- Carry hand sanitizer (alcohol-based) when away from home \checkmark
- Shower once daily and brush teeth with a soft toothbrush twice daily \checkmark
- \checkmark Wash fresh fruits and vegetables thoroughly before eating
- Clean cooking surfaces, counters, and utensils before using \checkmark
- \checkmark Store raw meat away from other foods and cook thoroughly before eating
- Ensure that you and those in your household are up to date on vaccines \checkmark
- Always use gloves when gardening/doing yard work \checkmark
- \checkmark Thaw foods in the refrigerator

DON'T

- Don't share personal items such as towels, razors, or toothbrushes (\mathbf{X})
- Don't get manicures or pedicures at salons or spas (\mathbf{X})
- (\mathbf{X}) Don't use rectal thermometers or suppositories
- Don't use tampons; use sanitary pads instead (\mathbf{X})
- Don't handle soil/dirt, and always use gloves when gardening/doing yard work (\mathbf{X})
- (\mathbf{X}) Don't clean up after pets with your bare hands
- Don't introduce live plants or fresh flowers to living area (\mathbf{X})
- Don't thaw foods at room temperature (\mathbf{X})









Managing neutropenia with your doctor

If you experience neutropenia during your treatment period, your doctor will work to help get your **neutrophil** (a type of white blood cell that fights infection) counts back up and resolve the neutropenia. Depending on when you experience neutropenia, your doctor may:



Periodic blood tests will be needed to monitor blood counts, including for levels of white blood cells. Your doctor will conduct these blood tests and manage neutropenia if it occurs.

Managing infections with your doctor

Depending on the type of infection, treatment will vary; however, antibiotics are usually prescribed to help fight infection. Fungal infections are most common in AML. Symptoms of a fungal infection are a fever, sore throat, cough, or tenderness or pain in the stomach. For more symptoms, see Section How do I know if I have neutropenia or an infection? on page 31. Your doctor may prescribe an antifungal along with your VENCLEXTA regimen to help reduce the risk of fungal infections.

Your doctor will work with you to help manage your treatment regimen with VENCLEXTA. This may include modifying or interrupting your dose.









What are more common side effects of **VENCLEXTA-based therapy?**

You may experience side effects that also impact how you feel each day. Treatment may affect different parts of your body leading to different symptoms. The most common side effects of VENCLEXTA in combination with azacitidine, decitabine, or low-dose cytarabine in people with AML include:



Respiratory symptoms

- Shortness of breath
- Sore throat
- Cough

Digestive and stomach symptoms

- Nausea
- Diarrhea
- Vomiting
- Stomach (abdominal) pain
- Constipation



Blood-related symptoms

- Low platelet count (cells in blood that help it to stop bleeding after a cut)
- Fever with low white blood cell count
- Low white blood cell count
- Low red blood cell count



Neurological symptoms

Dizziness



General symptoms

- Tiredness
- Infection in your blood
- Infection in lungs
- Muscle and joint pain
- Swelling of arms, legs, hands, or feet
- Fever
- Rash

- Low blood pressure
- Bleeding

Your healthcare provider may delay or decrease your dose or stop treatment if you have side effects. Don't stop or change your dose unless directed by your healthcare provider. VENCLEXTA may cause fertility problems in men. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of VENCLEXTA. Call your healthcare provider for medical advice about side effects.

You may report side effects to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.











STAYING **ON TRACK**











Follow these simple tips to plan your schedule:

- Take VENCLEXTA at the same time each day \checkmark
- Set a daily reminder alarm for 30 minutes before your chosen dose time
- Use the dosing calendar that we have provided on the next \checkmark page of this brochure to help you follow your healthcare team's directions
- Use a journal to write down all potential side effects, as well as any medicines you take, so that you can discuss these details with your healthcare provider

What happens if I miss a dose?



LESS than 8 hours from your scheduled dose?

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

MORE than 8 hours from your scheduled dose?

- **DO NOT** take the missed dose
- Take the next dose the following day at your usual scheduled time









VENCLEXTA dosing calendar

Keep track of when you take your medication. Print out this page to keep beyond 4 weeks.

> **Date of first VENCLEXTA dose:**

	Week 1	Week 2	Week 3	Week 4
Sun				
Mon				











HELPFUL RESOURCES & MATERIALS

It is not known if VENCLEXTA is safe and effective in children.

Actor portrayal.

You are not alone in living with AML.

Contact any of the organizations on the next page to find out more about how they can help you!













Learn more about living with AML

Get additional information about AML and connect with advocacy groups.



Foundation	1-600-500-9976	lymphoma.org
CancerCare	1-800-813-4673	cancercare.org
American Cancer Society	1-800-227-2345	cancer.org
National Cancer Institute	1-800-422-6237	cancer.gov
Patient Advocate Foundation	1-800-532-5274	patientadvocate.org

Information provided by AbbVie and Genentech is meant for informational purposes only. It is not meant to replace your healthcare provider's medical advice or treatment. The organizations listed above have not endorsed AbbVie and Genentech or any of their respective products or services. AbbVie and Genentech have listed these organizations only as a convenience and according to the permissions granted by their respective terms of use. Each organization has its own terms and conditions and privacy policy that you should read if you choose to contact any of them.











Support options

Living with a serious illness can come with many challenges, and getting your medicine shouldn't be one of them. We offer several types of assistance to help you.

> **Co-pay assistance for patients with private insurance** (for example, through employers)



If you have commercial health insurance and meet other eligibility criteria, the Genentech Oncology® Co-pay Assistance **Program*** may be able to help you pay for your medicine. With this program, you pay as little as \$0 co-pay per prescription for VENCLEXTA + azacitidine, or VENCLEXTA + decitabine, or VENCLEXTA + low-dose cytarabine, up to a \$25,000 yearly limit.

Visit CopayAssistanceNow.com to apply or call 1-855-MYCOPAY (1-855-692-6729) to find out if you qualify.

*The Co-pay Program is valid ONLY for patients with commercial (private or non-governmental) insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medicine. Patients using Medicare, Medicaid or any other federal or state government program (collectively, "Government Programs") to pay for their Genentech medicine are not eligible.

Under the Program, the patient may pay a co-pay. The final amount owed by a patient may be as little as \$0 for the Genentech medicine (see Program specific details). The total patient out-of-pocket cost is dependent on the patient's health insurance plan. The Program assists with the cost of the Genentech medicine only. It does not assist with the cost of other medicines, procedures or office visit fees. After reaching the maximum annual Program benefit amount, the patient will be responsible for all remaining out-of-pocket expenses. The Program benefit amount cannot exceed the patient's out-ofpocket expenses for the cost associated with the Genentech medicine.

All participants are responsible for reporting the receipt of all Program benefits as required by any insurer or by law. The Program is only valid in the United States and U.S. Territories, is void where prohibited by law and shall follow state restrictions in relation to AB-rated generic equivalents (e.g., MA, CA) where applicable. No party may seek reimbursement for all or any part of the benefit received through the Program. The Program is intended for the patient. Only the patient using the Program may receive the funds made available through the Program. The Program is not intended for third parties who reduce the amount available to the patient or take a portion for their own purposes. Patients with health plans that redirect Genentech Program assistance intended for patient out-of-pocket costs may be subject to alternate Program benefit structures. Genentech reserves the right to rescind, revoke or amend the Program without notice at any time.

Additional terms and conditions apply. Please visit the Co-pay Program website for the full list of Terms and Conditions.

Financial assistance for insured or uninsured patients

If you need help with the co-pay for your VENCLEXTA, VENCLEXTA Access Solutions can refer you to an independent co-pay assistance foundation.⁺ You may be able to get help paying for your medicine, no matter what type of health insurance you have.

To find out if you're eligible, visit **www.genentech-access.com/patient** or call 1-888-249-4918.

The Genentech Patient Foundation[‡] gives free Genentech medicine to people who don't have insurance coverage or who have financial concerns and meet eligibility criteria.

Call 888-941-3331 to speak to a Foundation Specialist to see if you qualify.

- † Independent co-pay assistance foundations have their own rules for eligibility. We cannot guarantee a foundation will help you. We only can refer you to a foundation that supports your disease state. We do not endorse or show financial preference for any particular foundation. The foundations we refer you to are not the only ones that might be able to help you.
- ‡ If you have health insurance, you must have already tried other types of financial assistance. You also need to meet income requirements. If you do not have insurance, or if your insurance does not cover VENCLEXTA, you must meet different income requirements.











Please see Important Safety Information on pages 28 to 29. Please see full Prescribing Information, including Medication Guide, at www.rxabbvie.com/pdf/venclexta.pdf.



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