

MEDICATION GUIDE
VENCLEXTA™ (ven-KLEKS-tuh)
(venetoclax)
tablets

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 doctor 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 doctor will do blood tests in your first 5 weeks of treatment to check you for TLS during treatment with VENCLEXTA. It is important to keep your appointments for blood tests. Tell your doctor 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

Drink plenty of water when taking 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 doctor may delay, decrease your dose, or stop treatment with VENCLEXTA if you have side effects.

See "**What are the possible side effects of VENCLEXTA?**" for more information about side effects.

What is VENCLEXTA?

VENCLEXTA is a prescription medicine used to treat people with chronic lymphocytic leukemia (CLL) with 17p deletion, who have received at least one prior treatment.

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

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.

- **Tell your doctor 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 doctor.

What should I tell my doctor before taking VENCLEXTA?

Before taking VENCLEXTA, tell your doctor 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 doctor tells you it is okay. If you are not sure about the type of immunization or vaccine, ask your doctor. 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 doctor should do a pregnancy test before you start treatment with VENCLEXTA. Females who are able to become pregnant 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 doctor 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.

Tell your doctor 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. See **“Who should not take VENCLEXTA?”**

How should I take VENCLEXTA?

- Take VENCLEXTA exactly as your doctor tells you to take it. Do not change your dose of VENCLEXTA or stop taking VENCLEXTA unless your doctor tells you to.
- When you first take VENCLEXTA:
 - You may need to take VENCLEXTA at the hospital or clinic to monitor for TLS.
 - Your doctor will start VENCLEXTA at a low dose. Your dose will be slowly increased weekly over 5 weeks up to the full dose. Read the Quick Start Guide that comes with VENCLEXTA before your first dose.
- Follow the instructions about drinking water described in the section of this Medication Guide about TLS called **“What is the most important information I should know about VENCLEXTA?”** and also in the Quick Start Guide.
- 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.
- 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 should I avoid while taking VENCLEXTA?

- You should not drink grapefruit juice, 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:

- See **“What is the most important information I should know about VENCLEXTA?”**
- **Low white blood cell count (neutropenia).** Low white blood cell counts are common with VENCLEXTA, but can also be severe. Your doctor will do blood tests to check your blood counts during treatment with VENCLEXTA. Tell your doctor right away if you have a fever or any signs of an infection while taking VENCLEXTA.

The most common side effects of VENCLEXTA include:

- diarrhea
- nausea
- low red blood cell count
- upper respiratory tract infection
- low platelet count
- feeling tired

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

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of VENCLEXTA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VENCLEXTA?

- Store VENCLEXTA at or below 86°F (30°C).
- Keep VENCLEXTA tablets in the original package during the first 4 weeks of treatment. **Do not** transfer the tablets to a pillbox or other container.

Keep VENCLEXTA and all medicines out of reach of children.

General information about the safe and effective use of VENCLEXTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VENCLEXTA for a condition for which it was not prescribed. Do not give VENCLEXTA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about VENCLEXTA that is written for health professionals.

What are the ingredients in VENCLEXTA?

Active ingredient: venetoclax

Inactive ingredients: copovidone, colloidal silicon dioxide, polysorbate 80, sodium stearyl fumarate, and calcium phosphate dibasic. The 10 mg and 100 mg coated tablets also include the following: iron oxide yellow, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide. The 50 mg coated tablets also include the following: iron oxide yellow, iron oxide red, iron oxide black, polyvinyl alcohol, talc, polyethylene glycol, and titanium dioxide.

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