

Use

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

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 doctor will do tests for TLS. It is important to keep your appointments for blood tests. 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. 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, or 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.

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.
- 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, and you should use effective birth control during treatment and for 30 days after the last dose of VENCLEXTA.
- Are breastfeeding or plan to breastfeed. It is not known if VENCLEXTA passes into your breast milk. Do not breastfeed during treatment with VENCLEXTA.

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 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.

The most common side effects of VENCLEXTA include diarrhea, nausea, low red blood cell count, upper respiratory tract infection, low platelet count, and 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.

These are not all the possible side effects of VENCLEXTA. Tell your doctor if you have any side effect that bothers you or that does not go away.