

Package leaflet: Information for the patient

Venclyxto 10 mg film-coated tablets
Venclyxto 50 mg film-coated tablets
Venclyxto 100 mg film-coated tablets
venetoclax

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Venclyxto is and what it is used for
2. What you need to know before you take Venclyxto
3. How to take Venclyxto
4. Possible side effects
5. How to store Venclyxto
6. Contents of the pack and other information

1. What Venclyxto is and what it is used for

What Venclyxto is

Venclyxto is a cancer medicine that contains the active substance venetoclax. It belongs to a group of medicines called “BCL-2 inhibitors”.

What Venclyxto is used for

Venclyxto is used to treat adults with:

- chronic lymphocytic leukaemia (CLL). Venclyxto may be given to you in combination with other medicines or alone.
- acute myeloid leukaemia (AML). Venclyxto will be given in combination with other medicines.

CLL is a type of cancer affecting white blood cells called lymphocytes and the lymph nodes. In CLL, the lymphocytes multiply too quickly and live for too long, so that there are too many of them in the blood.

AML is a type of cancer affecting white blood cells called myeloid cells. In AML, myeloid blood cells multiply and grow very quickly in bone marrow and blood, so that there are too many of them and not enough red blood cells in the blood.

How Venclyxto works

Venclyxto works by blocking a protein in the body called “BCL-2”. This protein is present in high amounts in some cancer cells and helps cancer cells survive. Blocking this protein helps to kill and lower the number of cancer cells. It also slows down the worsening of the disease.

2. What you need to know before you take Venclyxto

Do not take Venclyxto if:

- you are allergic to the active substance venetoclax or any of the other ingredients of this medicine (listed in section 6).
- you have CLL and are taking any of the medicines listed below when you start your treatment and while your dose is gradually being increased (usually over 5 weeks). This is because serious and life-threatening effects can occur when Venclxyto is taken with these medicines:
 - itraconazole ketoconazole, posaconazole, or voriconazole for fungal infections
 - clarithromycin for bacterial infections
 - ritonavir for HIV infection.

When your Venclxyto dose has been increased to the full standard dose, check with your doctor if you can start taking these medicines again.

- you are taking a herbal medicine called St. John's wort, used for depression. If you are not sure about this, talk to your doctor, pharmacist or nurse before taking Venclxyto.

It is important that you tell your doctor, pharmacist, or nurse about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your doctor may need to stop certain medicines when you first start taking Venclxyto and during the first days or weeks when your dose is increased to the full standard dose.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Venclxyto if:

- you have any kidney problems as your risk for a side effect called tumour lysis syndrome may increase
- you have liver problems as this may increase your risk for side effects. Your doctor may need to reduce your dose of Venclxyto
- you think you may have an infection or have had a long-lasting or repeated infection
- you are due to have a vaccine.

If any of the above apply to you, or you are not sure, talk to your doctor, pharmacist, or nurse before taking this medicine.

Tumour Lysis Syndrome

Some people may develop unusual levels of some body salts (such as potassium and uric acid) in the blood caused by the fast breakdown of cancer cells during treatment. This may lead to changes in kidney function, abnormal heartbeat, or seizures. This is called tumour lysis syndrome (TLS). The risk for TLS is in the first days or weeks of treatment with Venclxyto, as you increase your dose.

If you have CLL

Your doctor, pharmacist or nurse will do blood tests to check for TLS.

Your doctor will also give you medicines to help prevent the build-up of uric acid in your body before you start treatment with Venclxyto.

Drinking plenty of water, at least 1.5 to 2 litres per day, helps to remove cancer cell breakdown products from your body through urine and may decrease your risk of getting TLS (see section 3).

Tell your doctor, pharmacist, or nurse immediately if you get any of the symptoms of TLS listed in section 4.

If you are at risk of TLS you may be treated in hospital so that you can be given fluids into the vein if needed, have blood tests done more often and to check for side effects. This is to see if you can continue to take this medicine safely.

If you have AML

You may be treated in hospital and your doctor or nurse will make sure that you have enough water/fluids, give you medicines to prevent the build-up of uric acid in your body and do blood tests before you start to take Venclxyto, while they increase your dose and when you start to take the full dose.

Children and adolescents

Venclxyto should not be used in children and adolescents. This is because it has not been studied in these age groups.

Other medicines and Venclxyto

Tell your doctor or pharmacist if you take any of the following medicines as they can increase or decrease the amount of venetoclax in your blood:

- medicines for fungal infections – fluconazole, itraconazole, ketoconazole, posaconazole, or voriconazole
- antibiotics to treat bacterial infections – ciprofloxacin, clarithromycin, erythromycin, nafcillin, or rifampicin
- medicines to prevent seizures or to treat epilepsy – carbamazepine, phenytoin
- medicines for HIV infection – efavirenz, etravirine, ritonavir
- medicines to treat raised blood pressure or angina – diltiazem, verapamil
- medicines to lower cholesterol levels in the blood – cholestyramine, colestipol, colestevlam
- a medicine used to treat a lung condition called pulmonary arterial hypertension – bosentan
- a medicine to treat sleep disorder (narcolepsy) known as modafinil
- a herbal medicine known as St. John’s wort

Your doctor may change your dose of Venclxyto.

Tell your doctor if you take any of the following medicines as Venclxyto may affect how they work:

- medicines that prevent blood clots, warfarin, dabigatran
- a medicine used to treat heart problems known as digoxin
- a medicine for cancer known as everolimus
- a medicine used to prevent organ rejection known as sirolimus
- medicines to lower cholesterol levels in the blood known as statins

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, herbal medicines and supplements. This is because Venclxyto may affect the way some other medicines work. Also, some other medicines can affect the way Venclxyto works.

Venclxyto with food and drink

Do not eat grapefruit products, Seville oranges (bitter oranges, often used in marmalades), or starfruit (carambola) while you are taking Venclxyto – this includes eating them, drinking the juice or taking a supplement that might contain them. This is because they can increase the amount of venetoclax in your blood.

Pregnancy

- Do not get pregnant while you are taking this medicine. If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before taking this medicine.
- Venclxyto should not be used during pregnancy. There is no information about the safety of venetoclax in pregnant women.

Contraception

- Women of childbearing age must use a highly effective method of contraception during treatment and for at least 30 days after receiving Venclxyto to avoid becoming pregnant. If you are using hormonal contraceptive pills or devices, you must also use a barrier method of contraception (such as condoms) as the effect of hormonal contraceptive pills or devices may be affected by Venclxyto.
- Tell your doctor immediately if you become pregnant while you are taking this medicine.

Breast-feeding

Do not breast-feed while you are taking this medicine. It is not known whether the active substance in Venclyxto passes into breast milk.

Fertility

Based on findings in animals, Venclyxto may cause male infertility (low or no sperm count). This may affect your ability to father a child. Ask your doctor for advice on sperm storage before starting treatment with Venclyxto.

Driving and using machines

You may feel tired or dizzy after taking Venclyxto, which may affect your ability to drive or use tools or machines. If this happens, do not drive or use any tools or machines.

Venclyxto contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium free”.

3. How to take Venclyxto

Always take this medicine exactly as your doctor, pharmacist, or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

How much to take**If you have CLL**

You will begin treatment with Venclyxto at a low dose for 1 week. Your doctor will gradually increase the dose over the next 4 weeks to the full standard dose. For the first 4 weeks you will get a new pack each week.

- the starting dose is 20 mg (two 10 mg tablets) once a day for 7 days.
- the dose will be increased to 50 mg (one 50 mg tablet) once a day for 7 days.
- the dose will be increased to 100 mg (one 100 mg tablet) once a day for 7 days.
- the dose will be increased to 200 mg (two 100 mg tablets) once a day for 7 days.
- the dose will be increased to 400 mg (four 100 mg tablets) once a day for 7 days.
 - When you are receiving Venclyxto therapy alone, you will stay on the 400 mg daily dose, which is the standard dose, for as long as necessary.
 - When you are receiving Venclyxto therapy in combination with rituximab, you will receive the 400 mg daily dose for 24 months.
 - When you are receiving Venclyxto therapy in combination with obinutuzumab, you will receive the 400 mg daily dose for approximately 10 months.

Your dose may need to be adjusted for side effects. Your doctor will advise what your dose should be.

If you have AML

You will begin treatment with Venclyxto on a lower dose. Your doctor will gradually increase the dose each day for the first 3 or 4 days (depending on what medicine you take Venclyxto with). After 3 or 4 days you will take the full standard dose. The dose (tablets) is taken once a day.

Doses are listed in the table below

Day	Venclyxto daily dose	
1	100 mg (One 100 mg tablet)	
2	200 mg (Two 100 mg tablets)	
3	400 mg (Four 100 mg tablets)	
4 and beyond	400 mg (Four 100 mg tablets) when you take Venclyxto in combination with azacitidine or decitabine	600 mg (Six 100 mg tablets) when you take Venclyxto in combination with cytarabine

Your doctor will give you Venclyxto in combination with another medicine (azacitidine or decitabine or low-dose cytarabine). You will keep taking Venclyxto at the full dose until either your AML gets worse or you cannot take Venclyxto as it is causing serious side effects.

How to take Venclyxto

- Take the tablets with a meal at around the same time each day
- Swallow the tablets whole with a glass of water
- Do not chew, crush, or break the tablets
- During the first days or weeks of treatment as you increase the dose, you should take the tablets in the morning to help you follow-up with blood tests, if needed.

If you vomit after taking Venclyxto, do not take an extra dose that day. Take the next dose at the usual time the next day. If you have problems taking this medicine, talk to your doctor.

Drink plenty of water

If you have CLL

It is very important that you drink plenty of water when taking Venclyxto during the first 5 weeks of treatment. This will help to remove cancer cell breakdown products from your blood through your urine.

You should start drinking at least 1.5 to 2 litres of water daily two days before starting Venclyxto. You may also include non-alcoholic and non-caffeinated drinks in this amount, but exclude grapefruit, Seville orange, or starfruit (carambola) juices. You should continue to drink at least 1.5 to 2 litres of water on the day you start Venclyxto. Drink the same amount of water (at least 1.5 to 2 litres daily) two days before and on the day that your dose is increased.

If your doctor thinks that you are at risk of TLS, you may be treated in the hospital so that you can be given extra fluids into the vein if needed, have your blood tests more often and be checked for side effects. This is to see if you can continue to take this medicine safely.

If you have AML

It is very important you drink plenty of water when taking Venclyxto especially when you start treatment and increase your dose. Drinking water will help to remove cancer cell breakdown products from your blood through your urine. Your doctor or nurse will give you fluids into the vein if needed if you are in hospital to make sure this happens.

If you take more Venclyxto than you should

If you take more Venclyxto than you should, talk to your doctor, pharmacist, or nurse or go to hospital immediately. Take the tablets and this leaflet with you.

If you forget to take Venclyxto

- If it is less than 8 hours since the time you usually take your dose, take it as soon as possible.
- If it is more than 8 hours since the time you usually take your dose, do not take the dose that day. Return to your normal dose schedule the next day.

- Do not take a double dose to make up for a forgotten dose.
- If you are not sure talk to your doctor, pharmacist, or nurse.

Do not stop taking Venclxyto

Do not stop taking this medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following serious side effects may happen with this medicine:

Tumour lysis syndrome (common – may affect up to 1 in 10 people)

Stop taking Venclxyto and seek medical attention immediately if you notice any of the symptoms of TLS:

- fever or chills
- feeling or being sick (nausea or vomiting)
- feeling confused
- feeling short of breath
- irregular heart beat
- dark or cloudy urine
- feeling unusually tired
- muscle pain or uncomfortable joints
- fits or seizures
- abdominal pain and distension

Low white blood cell count (neutropenia) and infections (very common – may affect more than 1 in 10 people)

Your doctor will check your blood count during treatment with Venclxyto. Low white blood cell count can increase your risk for infection. Signs may include fever, chills, feeling weak or confused, cough, pain or burning feeling when passing urine. Some infections such as pneumonia or blood infection (sepsis) can be serious and may lead to death. Tell your doctor immediately if you have signs of an infection while taking this medicine.

Tell your doctor if you notice any of the following side effects:

If you have CLL

Very common (may affect more than 1 in 10 people)

- pneumonia
- upper respiratory tract infection – signs include runny nose, sore throat or cough
- diarrhoea
- feeling or being sick (nausea or vomiting)
- constipation
- feeling tired

Blood tests may also show

- lower number of red blood cells
- lower number of white blood cells called lymphocytes
- higher level of potassium
- higher level of a body salt (electrolyte) called phosphate
- lower level of calcium

Common (may affect up to 1 in 10 people)

- severe infection in the blood (sepsis)
- urinary tract infection
- low number of white blood cells with fever (febrile neutropenia)

Blood tests may also show:

- higher level of creatinine
- higher level of urea

If you have AML

Very common (may affect more than 1 in 10 people)

- feeling or being sick (nausea or vomiting)
- diarrhoea
- mouth sores
- feeling tired or weak
- infection of lung or blood
- decreased appetite
- joint pain
- dizziness or fainting
- headache
- shortness of breath
- bleeding
- low blood pressure
- urinary tract infection
- weight loss
- pain in belly (abdominal pain)

Blood tests may also show

- lower number of platelets (thrombocytopenia)
- lower number of white blood cells with fever (febrile neutropenia)
- lower number of red blood cells (anaemia)
- higher level of total bilirubin
- low level of potassium in the blood

Common (may affect up to 1 in 10 people)

- gall stones or gall bladder infection

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Venclyxto

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Venclyxto contains

The active substance is venetoclax.

- Venclyxto 10 mg film-coated tablets: Each film-coated tablet contains 10 mg venetoclax.
- Venclyxto 50 mg film-coated tablets: Each film-coated tablet contains 50 mg venetoclax.
- Venclyxto 100 mg film-coated tablets: Each film-coated tablet contains 100 mg venetoclax.

The other ingredients are:

- In the tablet core: copovidone (K 28), polysorbate 80 (E433), colloidal anhydrous silica (E551), anhydrous calcium hydrogen phosphate (E341 (ii)), sodium stearyl fumarate.

In the film-coating:

- Venclyxto 10 mg film-coated tablets: iron oxide yellow (E172), polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b).
- Venclyxto 50 mg film-coated tablets: iron oxide yellow (E172), iron oxide red (E172), iron oxide black (E172), polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b)
- Venclyxto 100 mg film-coated tablets: iron oxide yellow (E172), polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 3350 (E1521), talc (E553b).

What Venclyxto looks like and contents of the pack

Venclyxto 10 mg film-coated tablet is pale yellow, round 6 mm diameter, with V on one side and 10 on the other.

Venclyxto 50 mg film-coated tablet is beige, oblong 14 mm long, with V on one side and 50 on the other.

Venclyxto 100 mg film-coated tablet is pale yellow, oblong 17.2 mm long, with V on one side and 100 on the other.

Venclyxto tablets are provided in blisters which are packed in cartons as follows:

Venclyxto 10 mg film-coated tablets:

- 10 tablets (5 blisters each with 2 tablets)
- 14 tablets (7 blisters each with 2 tablets)

Venclyxto 50 mg film-coated tablets:

- 5 tablets (5 blisters each with 1 tablet)
- 7 tablets (7 blisters each with 1 tablet)

Venclyxto 100 mg film-coated tablets:

- 7 tablets (7 blisters each with 1 tablet)
- 14 tablets (7 blisters each with 2 tablets)
- 112 (4 x 28) tablets (4 cartons of 7 blisters each with 4 tablets).

Not all pack sizes may be marketed.

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