

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

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 patients with chronic lymphocytic leukaemia (CLL).

Venclyxto may be given to you in combination with other medicines or alone.

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.

How Venclyxto works

Venclyxto works by blocking a protein in the body called “BCL-2”. This protein 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 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 Venclyxto is taken with these medicines:
 - itraconazole ketoconazole, posaconazole, or voriconazole for fungal infections
 - clarithromycin for bacterial infections
 - ritonavir for HIV infection.

When your Venclyxto 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 Venclyxto.

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 Venclyxto and during the first five weeks when your dose is gradually increased to the full standard dose.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Venclyxto 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 Venclyxto
- 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 5 weeks of treatment with Venclyxto.

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

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

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.

Children and adolescents

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

Other medicines and Venclyxto

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 Venclyxto.

Tell your doctor if you take any of the following medicines as Venclyxto 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 Venclyxto may affect the way some other medicines work. Also, some other medicines can affect the way Venclyxto works.

Venclyxto with food and drink

Do not eat grapefruit products, Seville oranges (bitter oranges), or starfruit (carambola) while you are taking Venclyxto – 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.
- Venclyxto 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 Venclyxto 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 Venclyxto.
- 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 after taking Venclyxto, which may affect your ability to drive or use tools or machines.

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

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.

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 5 weeks of treatment, 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

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 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 Venclyxto

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 Venclyxto 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 Venclyxto. 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 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:**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

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.

United Kingdom

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 Venclxyto

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 Venclxyto contains

The active substance is venetoclax.

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

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

What Venclxyto looks like and contents of the pack

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

Venclxyto 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.

Marketing Authorisation Holder

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