Important Contact Details

My name:

My emergency contact (name and phone number):

Doctor's name – who prescribed Venclyxto:

Doctor's contact phone number:

https://medicinesauthority.gov.mt/rmm MT-VNCLY-250001 Date approved: May 2025

Important Safety Information for Healthcare Professionals about Venclyxto^{*} and TLS

This patient is taking Venclyxto[®] for CLL which may cause Tumour Lysis Syndrome (TLS) in the first 5 weeks of treatment.

- Evaluate blood chemistries: potassium, uric acid, phosphorus, calcium and creatinine.
- Urgently correct blood chemistry abnormalities. This can be fatal, if left untreated.
- If you suspect TLS, contact prescribing doctor listed on this card immediately.

Please consult the Summary of Product Characteristics (SmPC) or contact AbbVie's local representative V.J. Salomone Pharma Ltd. at +356 99644126 for more information and if you need additional copies of the patient card.

Patient Card

Safety Information about Venclyxto[®] (venetoclax) for Patients with Chronic Lymphocytic Leukaemia (CLL)

Venclyxto is used to treat patients with CLL. This card contains information you need to know aboutTumour Lysis Syndrome and Venclyxto^{*}.

You can report side effects directly using the Medicines Authority ADR reporting form, which is available online at <u>http://www.medicinesauthority.gov.mt/adrportal</u>, and sent by post or email to; Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Žammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 E-mail: posticensing.medicinesauthority@gov.mt

Alternatively, they may be reported by contacting AbbVie's local representative V.J. Salomone Pharma Ltd. at +35699644126.

Keep this patient card with you all the time.

- Show it to any doctor involved in your medicalcare or if you go to the emergency department.

- Always take Venclyxto[®] exactly as your doctorhas told you to.

What should I know about TLS?

During your treatment, you may develop high levels of certain body salts (such as potassium and uric acid) in the blood. This can lead to a condition called Tumour Lysis Syndrome (TLS) within the first 5 weeks of treatment.

TLS symptoms:

- fever or chills
- nausea or vomitingfeeling confused
- feeling short of breath
- irregular heart beat
- dark or cloudy urine
- feeling unusually tired
- muscle pain or joint pain
- fits or seizures
- abdominal pain and bloating

What should I do if I get TLS symptoms?

If you experience any TLS symptoms during your treatment, you should:

Call your doctor or seek medical attention immediately, and

1 Stop taking Venclyxto[®]

Read the Patient Information Leaflet (PIL) for more information.

How can I reduce my risk of getting TLS?



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Drink at least 1.5 to 2 litres of water daily:

- starting from 2 days before your first dose, and
 on the day of your first dose, and
 every day during first 5 weeks of treatment. Drinking plenty of water will help to remove high levels of blood salts through your urine.
- Attend your scheduled **blood test appointments**, as they will help your doctor identify TLS.
- Before your treatment with Venclyxto^{*}, start another medicine that helps prevent the build-upof the blood salt (uric acid) in your body, as instructed by your doctor.