VENCLEXTA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Venclexta?

Venclexta contains the active ingredient venetoclax. Venclexta is used to treat some specific blood cancers, including chronic lymphocytic leukaemia (CLL), small lymphocytic lymphoma (SLL) and acute myeloid leukaemia (AML).

For more information, see Section 1. Why am I taking Venclexta? in the full CMI.

2. What should I know before I take Venclexta?

Check the list of ingredients at the end of this CMI. Do not take Venclexta if you have ever had an allergic reaction to any of them.

Talk to your doctor before you take this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take Venclexta? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Venclexta and affect how it works, or Venclexta may interfere with other medicines and affect how they work.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Venclexta?

It is very important that you follow all directions carefully, particularly when you first start taking Venclexta. There can be serious consequences if you do not. These instructions can be found in Section 4. How do I take Venclexta? in the full CMI.

5. What should I know while taking Venclexta?

Things you should do	• Remind any doctor or dentist you visit that you are taking Venclexta. • Drink plenty of water every day when taking Venclexta.

	• Keep all your appointments, including those for blood tests.
Things you should not do	• Do not stop taking this medicine suddenly without checking with your doctor.
Driving or using machines	• Take care when driving or using machinery until you know how Venclexta affects you.
Drinking alcohol	• Drinking alcohol while you are taking Venclexta may make you feel sick or vomit.
Looking after your medicine	• Store Venclexta in a cool dry place away from direct sunlight.

For more information, see Section 5. What should I know while taking Venclexta? in the full CMI.

6. Are there any side effects?

The more serious side effects can include Tumour Lysis Syndrome (TLS), low white blood cell count (neutropenia) and infection.

For more information, including symptoms and what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

VENCLEXTA® (ven-cleks-tah)

Active ingredient: *Venetoclax* (ven-eat-oh-claks)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Venclexta. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Venclexta.**

Where to find information in this leaflet:

1. Why am I taking Venclexta?
2. What should I know before I take Venclexta?
3. What if I am taking other medicines?
4. How do I take Venclexta?
5. What should I know while taking Venclexta?
6. Are there any side effects?
7. Product details

1. Why am I taking Venclexta?

Venclexta contains the active ingredient venetoclax.

Venclexta is used to treat certain blood cancers, including:

- Chronic lymphocytic leukaemia (CLL), a condition where the blood and bone marrow contain too many of a type of white blood cells (lymphocytes).

- Small lymphocytic lymphoma (SLL), a condition where the lymph nodes contain too many of a type of white blood cells (lymphocytes).
- Acute myeloid leukaemia (AML), a condition where blood cells do not develop properly in the bone marrow. This results in a build-up of these immature cells in the blood and fewer red blood cells (that carry oxygen around the body), white blood cells (that fight infection) and/or platelets (that form clots when you are injured).

2. What should I know before I take Venclexta?

Warnings

Tumour Lysis Syndrome (TLS)

Tumour Lysis Syndrome (TLS), which can be fatal, has occurred rarely in patients receiving Venclexta.

There are some things you can do to help prevent TLS occurring:

- Follow all your doctor’s instructions carefully, especially when you start treatment with Venclexta.
- To help prevent TLS, it is important to stay hydrated and drink water every day when taking Venclexta. Particularly, starting two days before and on the day of your first dose of Venclexta, and every time the dose is increased, drink 6 to 8 glasses (approximately 1.5 to 2 litres total) of water each day.

- Keep all your appointments, including those for your blood tests, since the changes in your blood that can lead to TLS may not have any symptoms until the situation becomes very serious.
- Tell your doctor, nurse or pharmacist if you have or have had kidney problems, as this can increase the risk of TLS.
- Take any additional medicines your doctor may prescribe to help prevent TLS (if you are at higher risk).

Do not take Venclexta if:

1. you are allergic to venetoclax, or any of the ingredients listed at the end of this leaflet.
2. you are pregnant or think you might be pregnant.

Check with your doctor if you:

- have any problems with your liver or kidneys
- think you may have an infection
- have had any recent immunisations
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Tell your doctor immediately if you become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not take Venclexta if you are pregnant or are breastfeeding.

If you are a woman of child-bearing age, you must use a highly effective form of contraception during treatment with Venclexta and for at least 30 days after your last dose.

Male fertility

Venclexta may cause low sperm count in men. Ask your doctor for advice before starting treatment with Venclexta.

Use in Children

Do not give Venclexta to children younger than 18 years.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Venclexta and affect how it works.

For patients with CLL or SLL:

When you start treatment and during the time when the dose is gradually increased, do not take Venclexta and talk to your doctor if you are taking any of the following medicines:

- medicines used to treat or prevent fungal infections, including ketoconazole, posaconazole, voriconazole or itraconazole
- clarithromycin (a medicine used to treat infections caused by bacteria - antibiotic)
- conivaptan (a medicine used to treat low sodium levels)
- medicines used to treat HIV or hepatitis C infection, including ritonavir, indinavir, lopinavir or telaprevir.

For patients with CLL, SLL or AML:

Tell your doctor if you are taking any of the medicines listed below. Your doctor may need to change the dose of Venclexta.

Medicines that may <u>increase</u> the effect of Venclexta include:

- ketoconazole, posaconazole, voriconazole, itraconazole, fluconazole (medicines used to treat or prevent fungal infections)
- clarithromycin, ciprofloxacin, erythromycin (medicines used to treat infections caused by bacteria - antibiotic)

- conivaptan (a medicine used to treat low sodium levels)
- indinavir, lopinavir (medicines used to treat HIV)
- telaprevir (a medicine used to treat hepatitis C)
- ritonavir (a medicine used to treat HIV and hepatitis C)
- diltiazem, verapamil, captopril (medicines used to treat high blood pressure, angina and other heart conditions)
- felodipine (a medicine used to treat high blood pressure)
- dronedarone, amiodarone, quinidine (medicines used to treat certain heart conditions)
- rifampicin (a medicine used to treat tuberculosis and other serious infections)
- carvedilol (a medicine used to treat heart failure)
- ciclosporin (a medicine used to suppress the immune system to treat conditions like rheumatoid arthritis, nephrotic syndrome, psoriasis, transplant rejection)
- quercetin (a herbal product used for many conditions)
- ranolazine (a medicine used to treat angina)
- ticagrelor (a medicine used to help stop clots forming to reduce the chance of a heart attack, stroke).

Medicines that may <u>reduce</u> the effect of Venclexta include:

- azithromycin, nafcillin (medicines used to treat infections caused by bacteria - antibiotic)
- rifampicin (a medicine used to treat tuberculosis and other serious infections)

- carbamazepine, phenytoin (medicines used to prevent seizures, fits)
- *St John's wort* (a herbal product used to improve mood)
- bosentan (a medicine used to treat high blood pressure in the lungs)
- efavirenz, etravirine (a medicine used to treat HIV)
- modafinil (to treat certain sleep disorders).

Medicines where Venclexta may <u>increase</u> their effect: include:

- warfarin (a medicine used to thin the blood)
- digoxin (a medicine used to treat certain heart conditions)
- everolimus, (a medicine used to treat certain cancers)
- sirolimus (a medicine used to help in organ transplants).

Foods that may <u>increase</u> the effect of Venclexta include:

- grapefruit
- Seville oranges
- star fruit

(Including as juice, jams or marmalades).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Venclexta.

4. How do I take Venclexta?

How much to take

Two days before you start taking Venclexta, drink at least 6 to 8 glasses of water each day and continue to do this throughout your treatment, especially each time your dose is increased.

For patients with CLL or SLL:

You will start on a low dose and gradually increase as follows:

- Week 1: Take two 10 mg tablets together once every day
- Week 2: Take one 50 mg tablet once every day
- Week 3: Take one 100 mg tablet once every day
- Week 4: Take two 100 mg tablets together once every day
- Week 5: Take four 100 mg tablets all together once every day
- After week 5, continue to take four 100 mg tablets all together once every day.

Refer to the **Quick Start Guide** provided with your Starting Pack for instructions on which tablets to take and when to take them.

For patients with AML taking Venclexta in combination with azacitidine:

You will start on a low dose and gradually increase as follows:

- Day 1: Take one 100 mg tablet
- Day 2: Take two 100 mg tablets together
- Day 3: Take four 100 mg tablets all together
- After day 3, continue to take four 100 mg tablets all together once every day.

For patients with AML taking Venclexta in combination with low-dose cytarabine:

You will start on a low dose and gradually increase as follows:

- Day 1: Take one 100 mg tablet
- Day 2: Take two 100 mg tablets together
- Day 3: Take four 100 mg tablets all together
- Day 4: Take six 100 mg tablets all together
- After day 4, continue to take six 100 mg tablets all together once every day.

For CLL, SLL and AML, take Venclexta every day as instructed, until your doctor tells you to stop.

Do not break, crush or chew the tablets. Swallow them whole with a full glass of water.

In some instances, Venclexta needs to be taken with other medicines. Your doctor will let you know which medicines, how to take them and how long to take them.

When to take Venclexta

Take Venclexta during a meal or immediately after a meal at about the same time every day.

Please look for the QR code on the medicine pack. Scan this code with your smart phone for more information on Venclexta.

If you forget to take Venclexta

It is important that you take your medicine every day as prescribed.

If you miss your dose by less than 8 hours, take the tablet(s) as soon as you remember, and take the next dose at the usual time the next day.

If you miss your dose by more than 8 hours, skip the missed tablet(s) for that day and take your next tablets at the usual time the next day.

Do not take a double dose to make up for the dose you missed.

If you vomit after taking Venclexta

Do not take any extra tablets. Just take the correct dose the next day at your usual time.

If you take too much Venclexta

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there appear to be no signs of discomfort or poisoning.

5. What should I know while taking Venclexta?

Things you should do

Call your doctor straight away if you:

- think you may have symptoms of TLS, especially at the beginning of treatment, such as fever or chills, feeling sick or vomiting, being short of breath, changes in your heart rate, feeling unusually tired, dark cloudy urine, joint pain, feeling confused, convulsions.
- become pregnant while taking Venclexta.

Remind any doctor or dentist you visit that you are taking Venclexta.

Keep all your appointments, including those for blood tests.

Things you should not do

- Do not stop taking this medicine or change the dose without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Venclexta affects you.

Drinking alcohol

If you drink alcohol, symptoms, such as nausea and vomiting may be worse.

Looking after your medicine

Follow the instructions on the pack or bottle on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tumour Lysis Syndrome (TLS)

Tumour Lysis Syndrome (TLS) is caused by the rapid breakdown of cancer cells resulting in high levels of certain chemicals and low levels of calcium circulating in the blood. This situation can cause serious damage to the kidneys as well as other organs in the body.

Neutropenia

You may experience a low number of neutrophils (neutropenia), a type of white blood cells – this can be severe and need treatment. Your doctor or healthcare professional will check your blood counts during treatment with Venclexta.

Infections

You may experience infections during treatment with Venclexta. Some infections can be very serious or even fatal. Your doctor will closely monitor and treat you right away if you have fever or any signs of infection during treatment with Venclexta.

Less serious side effects

Less serious side effects	What to do
• diarrhoea • tummy pain • constipation • nausea (feeling sick) • vomiting • reduced appetite • weight loss • a sore inside the mouth • looking pale • feeling tired or weak • having little or no energy • shortness of breath when exercising • feeling dizzy or fainting • headache • trouble sleeping • low blood pressure • bleeding • swelling of your arms, legs, hands and feet.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Symptoms of TLS: • fever or chills • feeling sick or vomiting • being short of breath • feeling unusually tired • changes in your heart rate – slow, fast or irregular • your urine looks dark or cloudy • feeling confused • convulsions or fits • pain in the muscles or joints **Symptoms of an infection:** • fever or chills • feeling weak • feeling confused • cough, runny nose, sore throat • congestion on the chest	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• pain or burning when passing urine.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Venclexta contains

Active ingredient **(main ingredient)**	venetoclax

Other ingredients **(inactive ingredients)**	• copovidone • colloidal anhydrous silica • polysorbate 80 • sodium stearylfumarate • calcium hydrogen phosphate • iron oxide yellow • iron oxide red (50 mg tablet only) • iron oxide black (50 mg tablet only) • polyvinyl alcohol • macrogol 3350 • purified talc • titanium dioxide

Do not take this medicine if you are allergic to any of these ingredients.

Venclexta does not contain lactose or gluten.

What Venclexta looks like

Venclexta 10 mg tablets are pale yellow, round tablets with "V" on one side and "10" on the other. They are supplied in a blister pack containing 2 or 14 tablets (Aust R 267441).

Venclexta 50 mg tablets are beige, oblong tablets with "V" on one side and "50" on the other. They are supplied in a blister pack containing 1 or 7 tablets (Aust R 267444).

Venclexta 100 mg tablets are pale yellow, oblong tablets with "V" on one side and "100" on the other. They are supplied in:

- a bottle containing 120 tablets (Aust R 267445) and
- a blister pack containing 1, 7, 14 or 112 tablets (Aust R 267442).

For patients with CLL or SLL, Venclexta is available in a **Starting Pack**, which is designed to provide you with the first four weeks of your tablets. (Aust R 267443)

Each Starting Pack is presented as a carton containing four weekly wallets:

- Week 1 (14 x 10 mg tablets)
- Week 2 (7 x 50 mg tablets)
- Week 3 (7 x 100 mg tablets)
- Week 4 (14 x 100 mg tablets).

(Not all presentations may be available.)

Who distributes Venclexta?

Venclexta is distributed in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

MASCOT NSW 2020

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