Kymriah®

Consumer Medicine Information (CMI) summary

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

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Kymriah?

Kymriah, also known as tisagenlecleucel, is a type of medicine called a “genetically modified cell therapy”. It is made from some of your own white blood cells called T-cells. T-cells are important for your immune system (the body’s defenses) to work properly. A new gene is put into the T-cells so that they can target the cancer cells in your body.

Kymriah is used to treat B-cell precursor acute lymphoblastic leukaemia (B-cell ALL) in children and young adults up to 25 years of age, that is refractory, in relapse post-transplant, or in second or later relapse. It is also used to treat adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) after two or more lines of systemic therapy.

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

2. What should I know before I am given Kymriah?

Do not use if you have ever had an allergic reaction to tisagenlecleucel or any of the ingredients listed at the end of the CMI.

Talk to your doctor if 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 am given Kymriah? in the full CMI.

3. What if I am taking other medicines?

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

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

4. How will I receive Kymriah?

- Kymriah is made specially for you as a single, one-time treatment and will be given to you at a specialized treatment centre.

- Your doctor will give you Kymriah by infusion which means it will be given as a drip through a tube in your vein. This usually takes less than 1 hour.

More instructions can be found in Section 4. How you will I receive Kymriah? in the full CMI.

5. What should I know after I am given Kymriah?

Things you should do	• **Plan to stay within proximity (2 hours travel) from where you were treated for at least 4 weeks after you have been given Kymriah.** • **Remind any doctor, dentist or pharmacist you visit that you have been given Kymriah.** • **If you have surgery, tell the surgeon or anaesthetist that you have received Kymriah.** • **If you are about to have any blood tests, tell your doctor that you have received Kymriah.**
Things you should not do	• Do not donate blood, organs, tissues, sperms, oocytes and other cells.
Driving or using machines	• Do not drive, use machines or engage in activities that you need

Things you should do	• **Plan to stay within proximity (2 hours travel) from where you were treated for at least 4 weeks after you have been given Kymriah.** • **Remind any doctor, dentist or pharmacist you visit that you have been given Kymriah.** • **If you have surgery, tell the surgeon or anaesthetist that you have received Kymriah.** • **If you are about to have any blood tests, tell your doctor that you have received Kymriah.**
	to be alert for in the 8 weeks after receiving Kymriah.

For more information, see Section 5. What should I know after I am given Kymriah? in the full CMI.

6. Are there any side effects?

There can be some serious side effects before and after Kymriah treatment.

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

WARNING:

CYTOKINE RELEASE SYNDROME

Cytokine Release Syndrome (CRS), including fatal or life threatening reactions, occurred in patients receiving KYMRIAH. Do not administer KYMRIAH to patients with active infection or inflammatory disorders. Implement CRS management to treat severe or life threatening CRS with tocilizumab as per current guidelines.

IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, has occurred following treatment with KYMRIAH, including concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with KYMRIAH. Provide supportive care and/or corticosteroids as needed.

Kymriah®

Active ingredient(s): *tisagenlecleucel*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Kymriah. **You should also speak to your doctor or pharmacist if you would like further information or**

if you have any concerns or questions about using Kymriah.

Your doctor will give you a Patient Alert Card. Read it carefully and follow the instructions on it.

Where to find information in this leaflet:

1. Why am I using Kymriah?
2. What should I know before I am given Kymriah?
3. What if I am taking other medicines?
4. How will I receive Kymriah?
5. What should I know after I am given Kymriah?
6. Are there any side effects?
7. Product details

1. Why am I using Kymriah?

Kymriah (also known as tisagenlecleucel) is made from some of your own white blood cells called 'T-cells'. T-cells are important for your immune system (the body's defences) to work properly.

Kymriah is used to treat:

- Children and young adults up to 25 years of age with B-cell precursor acute lymphoblastic leukaemia (B-cell ALL) that is refractory, in relapse post-transplant, or in second or later relapse - a form of cancer that affects some types of white blood cells.
- Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy - a form of cancer that affects some types of white blood cells, mostly in the lymph nodes. Kymriah

is not used for patients with primary central nervous system lymphoma.

- Adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy - a form of cancer that affects some types of white blood cells, mostly in the lymph nodes.

How Kymriah works:

The T-cells are taken from your blood and a new gene is put into the T-cells so that they can target the cancer cells in your body. When Kymriah is infused into your blood, the modified T-cells find and kill the cancer cells.

2. What should I know before I am given Kymriah?

Warnings

Do not use Kymriah:

- If you are allergic to tisagenlecleucel, or any of the ingredients listed at the end of this leaflet including dimethyl sulfoxide (DMSO) and dextran 40.

Tell your doctor (or your doctor will check) if you:

- had a stem cell transplant in the last 4 months. Your doctor will check if you have signs or symptoms of graft versus host disease (GvHD). This happens when transplanted cells attack your body, causing symptoms

such as rash, nausea, vomiting, diarrhoea and bloody stools

- have any lung, heart, blood pressure or kidney problems
- notice that the symptoms of your lymphoma or leukaemia are getting worse. If you have leukaemia this might include fever, feeling weak, bleeding gums, bruising. If you have lymphoma, this might include unexplained fever, feeling weak, night sweats, sudden weight loss
- have had hepatitis B (HBV) or hepatitis C (HBC) or human immunodeficiency virus (HIV) infection
- had a vaccination in the previous 6 weeks or are planning to have one in the next few months
- have an infection.

Before you are given Kymriah, your doctor will:

- check your lung, heart, and blood pressure functions
- look for any signs of infection. Any active infection will be treated before administration of Kymriah.
- check if your lymphoma or leukemia is getting worse.
- check for signs of a medical complication called “graft versus host disease (GvHD)” that may occur usually after a prior transplant.
- check your blood for uric acid and how many cancer cells there are in the blood. This will show if you are likely to have ‘tumor lysis syndrome (TLS)’ - if needed, you will be given medicines to help reduce the chance of this.
- check if you have any antibody of hepatitis B or C or HIV in the blood.

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

Kymriah is not recommended during pregnancy. Women of child-bearing potential should use effective birth control after being given Kymriah. Your doctor will check if you are pregnant. Discuss pregnancy or fathering a child with your doctor if you are planning to have a baby after receiving Kymriah.

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

The effects of Kymriah in pregnant or breast feeding women are not known, and it may harm your unborn baby or your newborn/infant. If you become pregnant or think you may be pregnant after treatment with Kymriah, talk to your doctor immediately.

Sexually active males receiving Kymriah should use a condom during intercourse.

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 (such as corticosteroids) may interfere with Kymriah and affect how it works.

Talk to your doctor if you need to have any vaccinations.

You should not be given any "live" vaccines:

- in the 6 weeks before you are given a short course of chemotherapy to prepare your body for Kymriah cells (called "lymphodepleting" chemotherapy)
- during or after Kymriah treatment.

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

4. How will I receive Kymriah?

How much you will be given

- Kymriah is made from your own white blood cells
- Your doctor will collect some of your blood using a catheter placed in your vein (a procedure called ‘leukapheresis’). This can take 3 to 6 hours and may need to be repeated.
- Your white blood cells are frozen and sent away to manufacture Kymriah. It takes about 3 to 4 weeks to make Kymriah, but the time may vary. Your dose will consist of 1 or more infusion bags.
- Kymriah is a treatment manufactured specifically for you. There are situations where Kymriah cannot

be successfully manufactured. In some instances, a second manufacturing of Kymriah may be attempted.

When will you be given Kymriah

- While awaiting Kymriah manufacture, the underlying disease may worsen and progress.
- While Kymriah is being manufactured, additional therapy (a type of chemotherapy known as 'bridging therapy') may be needed to stabilize your cancer. This may induce side effects which can be severe or life-threatening. The treating physician will inform you about potential side effects of this therapy.
- Before you are given Kymriah, your doctor may give you a type of treatment called lymphodepleting chemotherapy for a few days to prepare your body.

How you are given Kymriah

- Kymriah will always be given to you by a qualified healthcare professional. Appropriate handling precautions will be taken as Kymriah contains human blood cells.
- During the 30 to 60 minutes before being given Kymriah you may receive other medicines to help to decrease infusion reactions and/or fever. These may include paracetamol and an antihistamine.
- Prior to Kymriah infusion, your doctor will check that your identity matches with the patient details on the Kymriah infusion bag(s). Kymriah is made from your own white blood cells **and should only be given to you.**

- Your doctor will give you Kymriah by infusion which means it will be given as a drip through a tube into your vein. This usually takes less than 1 hour.
- During the infusion your doctor will check if you have difficulty breathing or dizziness (possible symptoms of allergic reactions).
- Kymriah is given to you only once.

5. What should I know after I am given Kymriah?

Things you should do

Plan to stay within 2 hours travel of where you received treatment for at least 4 weeks after you have been given Kymriah. Your doctor will recommend that you return to the hospital 2 to 3 times a week for at least the first week. Your doctor will check to see if your treatment is working and help you with any side effects.

Call your doctor straight away if you:

- Have high fever, dizziness, light-headedness and blue discoloration of lips or limbs which may be symptoms of a serious condition called Cytokine Release Syndrome (CRS). Other symptoms of CRS are changes in heart rate, chills muscle pain, joint pain, nausea, vomiting, diarrhoea, excessive sweating, rash, loss of appetite, fatigue, headache, personality changes, confusion, inability to move part or all of the body, stiff neck, abnormal speech or eye movements, shortness of breath, heavy breathing, rapid breathing.

When occurring, these signs are almost always noticed within the first 10 days after infusion but can occur later.

- Experience neurological problems like altered or decreased awareness, delirium, anxiety, dizziness, tremor, headache, confusion, agitation, seizures, difficulty speaking and understanding speech and loss of balance. This is usually within the first 8 weeks after the infusion, but it can occur later as well. These may be symptoms of a condition called immune effector cell-associated neurotoxicity syndrome (ICANS).
- Have symptoms of fever, feeling weak, bleeding gums, bruising, night sweats, sudden weight loss. These may be signs of new lymphoma or leukemia from a type of white blood cells called T-cells.
- Experience feeling warm, fever, chills or shivering. These can be symptoms of an infection.
- Develop frequent infections with sore throat or mouth ulcers, these may be symptoms of a low level of white blood cells.
- Extreme tiredness, weakness and shortness of breath which may be symptoms of a lack of red blood cells.
- Bleeding or bruising more easily which may be symptoms of low levels of cells in the blood known as platelets.
- Have signs of serious allergic or hypersensitivity reactions such as difficulty breathing, dizziness.

Keep all appointments with your doctor

Your doctor will regularly check:

- your blood counts after you receive Kymriah as you may experience a decrease in the number of blood cells and blood components.
- for signs of cytokine release syndrome (CRS) or neurological problems.
- for signs that your lymphoma or leukaemia has returned or a new cancer occurs. If a new cancer occurs, your doctor or you should contact Novartis (1 800 671 203).
- for signs of CRS or neurological events (including ICANS).
- for signs and symptoms of infection. Some types of HIV testing may be affected, ask your doctor about this.
- for signs and symptoms of tumour lysis syndrome (TLS).

If you miss an appointment, call your doctor or the hospital as soon as possible to reschedule.

Remind any doctor, dentist or pharmacist you visit that you were given Kymriah.

If you are going to have surgery, tell the surgeon or anaesthetist that you were given Kymriah.

Things you should not do

Do not donate blood, organs, tissues, sperms, oocytes and other cells.

Driving or using machines

Do not drive, use machines or take part in activities that need you to be alert for. Kymriah can cause problems such as altered or decreased awareness or coordination and fits in the 8 weeks following infusion.

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.

Less serious side effects

Less serious side effects	What to do
Very common (more than 1 in 10 people) • Infusion reactions including fever, chills, shivering, nausea, vomiting, tiredness, dizziness, pain where the infusion needle is inserted, blisters, itching,	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
shortness of breath or wheezing • Side effects affecting the gut like loss of appetite, belly pain, nausea, vomiting, diarrhoea, constipation, weight loss • Side effects linked to your general condition including pain, fever, tiredness or chills • Side effects affecting the blood circulation including headache, dizziness *(symptoms of high blood pressure)* • Muscle weakness, muscle spasms, abnormal heart rhythm • Swollen ankles • Anxiety • Sleep disturbances • Cramps • Pain in the joints • Side effects affecting lungs and airways like coughing, rapid breathing, shortness	

Less serious side effects	What to do
of breath or laboured breathing • Rash • Personality changes, headaches, confusion, inability to move part or all of the body, stiff neck, abnormal speech and eye movements • Severe confusion (delirium) • Dizziness, lightheadedness *(symptoms of low blood pressure)* • Blue discolouration of the lips or limbs especially the hands or feet • Breathlessness • Severely decreased urine output **Common (up to 1 in 10 people)** • Rash, nausea, vomiting, diarrhoea including bloody stools (possible graft versus host disease)	

Less serious side effects	What to do
• Decreased urination and/or muscle spasms (twitches) *(possible symptoms of tumour lysis syndrome)* • Convulsions, fits (seizures) • Severe nerve pain • Swelling and buildup of fluid, swelling of limbs, face or general swelling • Swelling of the belly • Changes or loss of vision • Side effects linked to your general condition including sore throat, stuffy nose, joint or muscles aching, headache, dizziness • Side effects affecting the gut like bloating, mouth sores, dry mouth • Pain in muscles, pain in the bones, pain in the limbs, back pain • Side effects affecting the nervous system including involuntary	

Less serious side effects	What to do
shaking of the body (tremor), tingling or numbness, impaired memory or thinking, numbness or tingling in fingers or toes, uncontrollable movements or actions of the body including tremors, jerks, twitches, spasms, contractions or problem walking, difficulty in speaking or understanding speech • Side effects affecting the lungs and airways like difficulty breathing, painful breathing • Side effects affecting the skin including hot flushes, night sweats, itching, skin reddening, excessive sweating • Side effects affecting your metabolism including symptoms of high blood sugar (thirst, low urine output, dark urine, dry flushed skin, irritability) or possible	

Less serious side effects	What to do
symptoms of excess circulating blood volume (shortness of breath, labored breathing, breathlessness) • Liver and gall bladder side effects such as yellow skin and eyes • Temporary enlargement of organs *(due to increased pressure in the stomach)* • High fever, chills, difficulty breathing, yellow skin and eyes, bloody stools, severely decreased urine output *(multiple organ dysfunction syndrome resulting from increased pressure thereby reducing blood flow to organs)* • Tiredness, confusion, muscle twitching, convulsions • Extreme inflammation (caused by overactive immune cells	

Very common serious side effects

Serious side effects	What to do
• Signs and symptoms of **cytokine release syndrome** *(a condition caused by a large, rapid release of proteins called cytokines into the blood)* such as high fever, dizziness, light-headedness, blue discoloration of lips or limbs especially the hands and feet, shortness of breath, heavy breathing, rapid breathing, chills, muscle pain, joint pain, nausea, vomiting, loss of appetite, fatigue, changes in heart rate, headache, personality changes, confusion, inability to move part or all of the body, stiff neck, abnormal speech or eye movements • Signs and symptoms of **blood disorders** such as frequent infections,	**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
weakness, fatigue, fever, chills and/or shivering, sore throat, mouth ulcers, rash, swelling, yellow or pale skin, yellow eyes, sudden bleeding or bruising, uncontrolled bleeding, blood in the urine, breathlessness, abnormal body movement, irritability • Signs and symptoms of **heart failure, worsening of heart failure or cardiac arrest** such as fast and/ or irregular heartbeat, breathlessness, difficulty breathing when lying down, swelling of the legs or feet, stopped heartbeat • Signs and symptoms of infection such as feeling warm, fever, chills or shivering	

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.

Some side effects (for example problems with blood clotting, high levels of uric acid in the blood) can only be found when your doctor does laboratory tests from time to time to check your progress.

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.

7. Product details

Kymriah is only given in a qualified treatment centre.

What Kymriah contains

Active ingredient **(main ingredient)**	**Tisagenlecleucel** **Each infusion bag of Kymriah contains autologous T cells genetically modified to express an anti-CD19 chimeric antigen receptor. 1 or more bags contain a total of 1.2 x 10^6 to 6.0 x 10^8 CAR-positive viable T-cells.**
Other ingredients **(inactive ingredients)**	The cryo-media solution contains: • Potassium • Magnesium • Sodium • Aluminium • Acetate • Chloride • Dextran 40 • Glucose • Albumin (HSA) • Dimethyl sulfoxide (DMSO) • Dimethyl sulfone • D-gluconic acid

Active ingredient **(main ingredient)**	**Tisagenlecleucel** **Each infusion bag of Kymriah contains autologous T cells genetically modified to express an anti-CD19 chimeric antigen receptor. 1 or more bags contain a total of 1.2 x 10^6 to 6.0 x 10^8 CAR-positive viable T-cells.**
	• Acetytriptophan • Hydroxymethylfurfural • Caprylate Kymriah contains 24.3 to 121.5 mg sodium per dose, equivalent to 1% to 6% of the WHO recommended maximum daily intake of 2 g sodium for an adult. Kymriah contains potassium, less than 1 mmol (39mg) per dose, i.e. essentially "potassium free".

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

What Kymriah looks like

Kymriah is supplied as an infusion bag containing a cloudy to clear, colourless to slightly yellow suspension of cells (tisagenlecleucel). Each bag contains 10 mL to 50 mL of the suspension.

Kymriah is stored at or below minus 120°C. The product is thawed at bedside when it is ready to be used.

(Aust R 312686, 475975, 520806 and 521846).

Who distributes Kymriah

Kymriah is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

(ABN 18 004 244 160)

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