

YERVOY®

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.

1. Why am I given YERVOY?

YERVOY contains the active ingredient ipilimumab. YERVOY is used to treat various kinds of cancer.

For more information, see Section [1. Why am I using YERVOY?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to YERVOY 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 use YERVOY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with YERVOY 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 am I given YERVOY?

- YERVOY will be given to you in hospital or clinic under the supervision of an experienced doctor and/or nurse
- It will be given to you as an infusion (a drip) into a vein (intravenously)
- Your doctor will decide how many treatments you should be given

More instructions can be found in Section [4. How do I use YERVOY?](#) in the full CMI.

5. What should I know while receiving YERVOY?

Things you should do
<ul style="list-style-type: none">• Tell any other doctors, dentists, and pharmacists who are treating you that you are being given YERVOY• Ensure you tell your doctor if you have autoimmune

	<p>disease, any history of inflammation of the lungs, if you take anticoagulant therapy, if you have previously experienced a severe skin reaction on prior cancer therapy or if you are taking any medicines that suppress your immune system, such as corticosteroids</p> <ul style="list-style-type: none"> • YERVOY acts on your immune system and may cause inflammation in parts of your body which may be life threatening and need treatment or withdrawal of YERVOY • Tell your doctor immediately if you have any signs or symptoms of possible side effects or if they get worse despite medical care or management
Things you should not do	<ul style="list-style-type: none"> • Do not try to treat your symptoms with other medicines on your own without telling your doctor. Your doctor

	<p>may give you other medicines to prevent complications and reduce your symptoms, your doctor may withhold the next dose of YERVOY, or stop your treatment with YERVOY altogether</p>
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Do not drive or use machines after you have been given YERVOY unless you are sure that you are not affected • Notify your doctor if you notice any changes to your ability to drive or use machines

For more information, see Section [5. What should I know while receiving YERVOY?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, YERVOY can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious and you may require medical attention. Contact your doctor immediately or go to the Emergency Department at your nearest hospital if you have any signs or symptoms (changes to your

normal self), particularly if they are getting worse or do not go away.

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.

Both YERVOY and nivolumab act on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening.

These side effects are most likely to begin during treatment, however, side effects can show up months after your last infusion.

IT IS IMPORTANT TO TELL YOUR DOCTOR IMMEDIATELY IF YOU HAVE, OR DEVELOP, ANY OF THE SYMPTOMS LISTED UNDER POSSIBLE SIDE EFFECTS.

YERVOY® (yure-voy)

Active ingredient(s): *ipilimumab* (ipi-lim-u-mab)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I given YERVOY?](#)
- [2. What should I know before I am given YERVOY?](#)
- [3. What if I am taking other medicines?](#)

[4. How am I given YERVOY?](#)

[5. What should I know while receiving YERVOY?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I given YERVOY?

YERVOY contains the active ingredient ipilimumab. YERVOY is a protein which helps your immune system to attack and destroy cancer cells.

YERVOY as a single therapy is used to treat:

- Advanced skin cancer (unresectable or metastatic melanoma)

YERVOY in combination with nivolumab is used to treat:

- Advanced melanoma (unresectable or metastatic melanoma)
- A type of advanced kidney cancer (renal cell carcinoma)
- A type of cancer that affects the lining of the lung (Malignant pleural mesothelioma)
- A type of cancer of the food pipe (oesophageal squamous cell cancer)
- A type of liver cancer (unresectable or metastatic hepatocellular carcinoma)
- A type of cancer of the colon or rectum, together referred to as colorectal cancer or bowel cancer, that is shown by a laboratory test to have certain biological

markers (microsatellite instability-high [MSI-H] or mismatch repair deficient [dMMR]).

YERVOY in combination with nivolumab and chemotherapy is used to treat:

- A type of lung cancer (non-small cell lung cancer without certain biological markers)

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

Warnings

You should not be given YERVOY if:

- you are allergic to ipilimumab, or any of the ingredients listed in Section [7. Product details](#)

Always check the ingredients or talk to your doctor to make sure you can use this medicine.

Check with your doctor if you:

- have an autoimmune disease (a condition where the body attacks its own cells) like Crohn's, ulcerative colitis or lupus
- have any history of inflammation of the lungs
- if you take anticoagulant therapy. These are medicines which increase the risk of bleeding in the stomach and gut
- if you have previously experienced a severe skin reaction on prior cancer therapy

- are taking any medicines that suppress your immune system, such as corticosteroids, since these medicines may interfere with the effect of YERVOY. However, once you are treated with YERVOY, your doctor may give you corticosteroids to reduce any possible side effects that you may have during your treatment and this will not impact the effect of the medicine.

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, intend to become pregnant, or if you are breast-feeding.

You must not use YERVOY if you are pregnant unless your doctor specifically recommends it.

The effects of YERVOY in pregnant women are not known, but it is possible that the active substance, ipilimumab, could harm an unborn baby.

- You must use effective contraception while you are being treated with YERVOY if you are a woman who could become pregnant
- If you become pregnant while using YERVOY, tell your doctor

You should stop breast-feeding if you are being treated with YERVOY.

It is not known whether ipilimumab gets into breast milk. A risk to the breast-fed infant cannot be excluded.

Use in children or adolescents

- It is not recommended to use this medicine in children or an adolescent (below 18 years) until further information becomes available

Important information about some of the ingredients of YERVOY

- Tell your doctor if you are on a low-sodium (low-salt) diet before you are given YERVOY. This medicine contains 2.3 mg sodium per mL of concentrate.

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 (over the counter) from your pharmacy, supermarket or health food shop.

Ask your doctor for advice before taking any medicine or dietary supplement/vitamin during your 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 YERVOY.

4. How am I given YERVOY?

How is YERVOY given

- YERVOY will be given to you in hospital or clinic under the supervision of an experienced doctor
- It will be given to you as an infusion (a drip) into a vein (intravenously)
- Your doctor will decide how many treatments you should be given

Dosage and frequency of administration of YERVOY

- The recommended dose (amount) and frequency (timing) of YERVOY can be different depending on the type of cancer it is being used to treat
- Some types of cancer are treated with YERVOY in combination with other prescription anti-cancer medicines
- Your doctor will advise you which treatments you will be given and will tell you about the dose and frequency of these treatments
- Please refer to the Consumer Medicine Information of the other prescription anti-cancer medicines in order to understand the use of these other prescription anti-cancer medicines. If you have questions about these medicines, please ask your doctor

If you miss a dose of YERVOY

It is very important for you to keep all appointments to receive YERVOY. If you miss an appointment, ask your doctor when to schedule your next dose.

If you are given too much YERVOY

As YERVOY is given to you under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given YERVOY, tell your doctor immediately.

5. What should I know while receiving YERVOY?

Things you should do

Tell any other doctors, dentists, nurses and pharmacists who are treating you that you are being given YERVOY.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given YERVOY.

Call your doctor straight away if you:

- Have any signs or symptoms of possible side effects or if they get worse. See Section [6. Are there any side effects?](#)

- Develop symptoms of an allergic reaction. These symptoms may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

Things you should not do

Do not try to treat your symptoms with other medicines on your own without telling your doctor.

- Your doctor may:
- Give you other medicines in order to prevent complications and reduce your symptoms
- Withhold the next dose of YERVOY
- Or stop your treatment with YERVOY altogether

Please note that these signs and symptoms are sometimes delayed, and may develop weeks or months after your last dose. Before treatment, your doctor will check your general health. You will also have blood tests during treatment.

Take special care with YERVOY

- YERVOY is a medicine that influences your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life threatening and need treatment or withdrawal of YERVOY

- Tell your doctor immediately if you have any of the symptoms of inflammation listed in Section [6. Are there any side effects?](#)

Driving or using machines

Do not drive or use machines after you have been given YERVOY unless you are sure that you are not affected. Notify your doctor if you notice any changes to your ability.

Feeling tired or weak is a very common side effect of YERVOY. This can affect your ability to drive or operate any machinery. Patients should therefore be cautious after having received YERVOY.

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.

YERVOY alone or in combination may cause changes in the results of tests carried out by your doctor.

Serious side effects

Serious side effects	What to do
<p>Lung problems:</p> <ul style="list-style-type: none">• Problems with your lungs such as breathing difficulties, shortness of breath, or cough. These may be signs of inflammation of the lungs (pneumonitis or interstitial lung disease) <p>Stomach and Intestinal problems:</p> <ul style="list-style-type: none">• Inflammation of the intestines (colitis, enterocolitis, coeliac disease, pancreatic exocrine insufficiency), stomach (gastritis) and duodenum (duodenitis) which can worsen to bleeding or bowel perforation• Symptoms may include diarrhoea (watery, loose or soft stools), an increased number of bowel movements	<p>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.</p>

Serious side effects	What to do
<p>(an increase by two or more per day), constipation, vomiting, nausea, mucus and blood in your stools, or darker-coloured stools, stomach pain or tenderness in your stomach area</p> <p>Liver problems:</p> <ul style="list-style-type: none"> • Inflammation of the liver (hepatitis) • Symptoms may include yellowing of the eye or skin (jaundice), pain on the right side of your stomach area or tiredness <p>Kidney problems:</p> <ul style="list-style-type: none"> • Inflammation in the kidney (nephritis) • Signs and symptoms may include abnormal kidney function tests, decreased volume of urine and kidney failure (including abrupt loss of kidney function) 	

Serious side effects	What to do
<p>Hormone gland problems:</p> <ul style="list-style-type: none"> • Damage or inflammation of hormone producing glands. Symptoms may include headaches, blurry or double vision, fatigue, decreased sexual drive, behavioural changes. • Underactive function of the pituitary gland • Underactive function of the thyroid gland which can cause tiredness or weight gain • Overactive function of the thyroid which can cause rapid heart rate, sweating and weight loss • Decreased function of the adrenal glands caused by an underactive hypothalamus part of the brain) or an overactive pituitary gland (a small 	

Serious side effects	What to do
<p data-bbox="248 248 756 353">gland at the base of the brain)</p> <ul data-bbox="204 369 778 1249" style="list-style-type: none"> <li data-bbox="204 369 778 474">• Defect in gland producing sex hormones <li data-bbox="204 495 778 667">• Acid in the blood produced by diabetes (diabetic ketoacidosis) <li data-bbox="204 683 778 1249">• Excessive thirst, the passing of a greatly increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell (diabetes) <p data-bbox="204 1265 552 1317">Skin problems:</p> <ul data-bbox="204 1350 778 2038" style="list-style-type: none"> <li data-bbox="204 1350 778 1865">• Severe and possibly fatal peeling of the skin (toxic epidermal necrolysis, Steven-Johnson syndrome) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) <li data-bbox="204 1881 778 2038">• Signs and symptoms of severe skin reaction may include skin rash 	

Serious side effects	What to do
<p>with or without itching, peeling of the skin, dry skin, fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells) and effects on liver, kidneys or lungs</p> <ul style="list-style-type: none"> • Severe condition of the skin that causes red, often itchy spots, similar to rash of measles, which starts on the limbs and sometimes on the face and the rest of the body (erythema multiforme), skin disease with thickened patches of red skin, often silvery scales (psoriasis), hives (itchy, bumpy rash) <p>Brain and nervous system problems:</p> <ul style="list-style-type: none"> • Damage to nerves causing numbness and weakness, including in the extremities like hands or feet 	

Serious side effects	What to do
<p>(polyneuropathy, peripheral neuropathy)</p> <ul style="list-style-type: none"> • Inflammation of the brain (encephalitis) • A condition in which the muscles become weak and tire easily (myasthenic syndrome) • Inflammation of the nerves caused by the body attacking itself, causing numbness, weakness, tingling or burning pain (autoimmune neuropathy) • A temporary inflammation of the nerves that causes pain, weakness and paralysis in the extremities (Guillain Barre syndrome) • Dizziness • Excessive accumulation of fluid on the brain, • Difficulty in speaking 	

Serious side effects	What to do
<ul style="list-style-type: none"> • Damage to the nerves (causing pain, weakness and cramps) • Difficulty in coordinating movements (ataxia), shaking, twitching, brief involuntary muscle contraction • Inflammation of the nerves, foot drop (peroneal nerve palsy) • Triad of symptoms (meningism): neck stiffness, intolerance of bright light and headache • Inflammation of the tissue around the brain and spinal cord (aseptic meningitis) causing headache, neck stiffness (with or without fever), light sensitivity, muscle pain and altered levels of consciousness • Inflammation of the spinal cord (myelitis) causing back and neck pain, weakness in the 	

Serious side effects	What to do
<p>arms or legs, loss of bladder or bowel control</p> <p>Complications of allogeneic Haematopoietic Stem Cell Transplant (HSCT):</p> <ul style="list-style-type: none"> • Complications of stem cell transplant that uses donor cells (allogeneic) may occur after treatment with YERVOY. • These complications can be severe and can lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant. <p>Problems in other organs:</p> <ul style="list-style-type: none"> • Inflammation of the heart (myocarditis). Symptoms may include shortness of breath, fatigue, palpitations or chest pain. 	

Serious side effects	What to do
<ul style="list-style-type: none"> • Changes in the rhythm or rate of the heart, abnormal heart rhythm • Disease of blood vessels, low blood pressure, feeling intense heat with sweating and rapid heartbeat, weakness of the heart muscle, fluid around the heart • Inflammation of muscles (myositis). Symptoms may include muscle pain, stiffness, weakness, chest pain or severe fatigue • Muscle breakdown/ injury (rhabdomyolysis). Symptoms may include muscle pain, weakness, nausea or vomiting • Eye inflammation and vision changes. Symptoms may include redness in the eye, pain in the eye, flashes of lights or tiny specs in your vision, blurry vision 	

Serious side effects	What to do
<p>and short-term vision loss.</p> <ul style="list-style-type: none"> • Solid organ transplant rejection • A condition where the immune system mistakenly destroys red blood cells (oxygen carrying cells) and results in decreased number of red blood cells (autoimmune haemolytic anaemia) • A condition where the bone marrow fails to produce enough new blood cells (aplastic anaemia) which can result in anaemia (decreased red blood cells), and susceptibility to infection or bruising • A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (called 	

Serious side effects	What to do
<p>haemophagocytic lymphohistiocytosis). Symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems.</p> <ul style="list-style-type: none"> • A group of metabolic complications occurring after cancer treatment characterised by high blood levels of potassium and phosphate, and low blood levels of calcium (tumour lysis syndrome). • A condition where a combination of the heart, muscles, and nerves can become inflamed and weak – can cause chest pain, irregular heartbeats, severe muscle weakness or pain, and vision/ swallowing when used 	

Serious side effects	What to do
<p>in combination with nivolumab.</p> <p>Infusion reactions:</p> <ul style="list-style-type: none"> • Allergic reaction, reaction related to the infusion of the medicine • Life threatening allergic reaction • Hypovolaemic shock, causing rapid heart rate, shallow breathing, cool, clammy skin, confusion or dizziness 	

Other side effects

Other side effects	What to do
<p>The following side effects have been reported in clinical trials when YERVOY has been given alone:</p> <p>Very Common side effects</p> <ul style="list-style-type: none"> • Loss of appetite • Diarrhoea 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<ul style="list-style-type: none"> • Feeling sick (nausea) or being sick (vomiting) • Stomach pain • Itching, skin rash • Feeling tired or weak • Cough • Headache • Fever • Insomnia <p>Common side effects</p> <ul style="list-style-type: none"> • Serious bacterial infection of the blood (sepsis) • Tumour pain • Dehydration • Inflammation of the eye which causes pain and redness, blurred vision • Low blood pressure, temporary redness of the face and neck • Weight loss • Inflammation and redness of the skin, skin colour change in patches (vitiligo) • Hair loss or thinning 	

Other side effects	What to do
<ul style="list-style-type: none"> • Excessive sweating at night • Pain in the muscles and joints • Fever, shivering, lack of energy • Swelling, pain, reaction at site of injection • Confusion • Influenza like illness 	
<p>The following side effects have been reported in clinical trials when YERVOY has been given in combination with nivolumab:</p> <p>Very Common side effects</p> <ul style="list-style-type: none"> • Decreased appetite • Headache • Shortness of breath (dyspnoea) • Pain in the joints, muscles and bones • Feeling tired or weak • Fever <p>Common side effects</p>	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<ul style="list-style-type: none"> • Serious lung infection (pneumonia), infections of the upper respiratory tract • Dehydration • Inflammation of the eye, which causes pain and redness, blurred vision • Fast heart rate • High blood pressure (hypertension) • Mouth ulcers and cold sores (stomatitis), inflammation of the pancreas (pancreatitis), constipation, dry mouth • Pain in the muscles and bones • Inflammation of the joints (arthritis) • Oedema 	
<p>The following side effects have been reported in clinical trials when YERVOY has been given in combination with nivolumab and chemotherapy</p>	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<p>Very Common side effects</p> <ul style="list-style-type: none"> • Decreased appetite • Diarrhoea (watery, loose or soft stools), vomiting, nausea • Skin rash sometimes with blisters, itching • Feeling tired or weak <p>Common side effects</p> <ul style="list-style-type: none"> • Conjunctivitis • Serious lung infection (pneumonia), infections of the upper respiratory tract • Dry eyes • Headache • Shortness of breath (dyspnoea) • Mouth ulcers and cold sores (stomatitis), inflammation of the pancreas (pancreatitis), constipation, dry mouth • Dry skin, redness of the skin, unusual hair loss or thinning 	

Other side effects	What to do
<ul style="list-style-type: none"> • Pain in the joints, muscles and bones, inflammation of the joints • Fever • Oedema (swelling) 	

Tell your doctor, nurse 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 YERVOY contains

Active ingredient (main ingredient)	ipilimumab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• trometamol hydrochloride• sodium chloride• mannitol (E421)• pentetic acid• polysorbate 80• sodium hydroxide• hydrochloric acid• water for injections

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

What YERVOY looks like

YERVOY concentrate for solution for infusion is a clear to slightly opalescent, colourless to pale yellow liquid that may contain light (few) particulates and is supplied in a glass vial with a rubber stopper sealed with aluminium.

It is available in packs containing either 1 vial of 10 mL or 1 vial of 40 mL.

YERVOY is available in the following presentations:

- YERVOY (ipilimumab) concentrate solution for infusion 50 mg in 10 mL (5 mg/mL) AUST R 174319
- YERVOY (ipilimumab) concentrate solution for infusion 200 mg in 40 mL (5 mg/mL) AUST R 174322

Who distributes YERVOY

Bristol-Myers Squibb Australia Pty Ltd

Level 2, 4 Nexus Court

Mulgrave VIC 3170 Australia

Toll free number: 1800 067 567

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