

YERVOY®

(yure-voy)

Ipilimumab (ipi-lim-u-mab)

Consumer Medicine Information

WARNINGS AND PRECAUTIONS

Yervoy acts 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.

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about YERVOY. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving YERVOY against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

You should read this leaflet carefully and keep it in a safe place to refer to it later.

WHAT IS YERVOY USED FOR

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

Ipilimumab is used to treat advanced melanoma in adults.

YERVOY will be given to you in hospital under the supervision of an experienced doctor.

YERVOY will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 90 minutes.

Ask your doctor if you have any questions about why YERVOY has been prescribed for you.

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

BEFORE YOU ARE GIVEN YERVOY

You should not be given YERVOY

- if you are allergic (hypersensitive) to ipilimumab or any of the other ingredients of YERVOY. If you are not sure, talk to your doctor.

Check with your doctor or nurse before you are given YERVOY:

- if you take corticosteroids or immunosuppressive therapy. These are medicines which reduce the functioning of your immune system, and may make you more likely to develop infections and some cancers
- if you have an autoimmune disease (a condition where the body attacks its own cells).
- if you have, or have ever had, chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV).
- if you have a human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS).

- if you take anticoagulant therapy. These are medicines which increase the risk of bleeding in the stomach and gut.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Ask your doctor for advice before taking any medicine.

Children

It is not recommended to use this medicine in children or adolescents (below 18 years) until further data become available.

Take special care with YERVOY

YERVOY is a medicine that influences your immune system and may cause inflammation in parts of your body. Inflammation can cause serious damage to your body and some inflammatory conditions may be irreversible or life-threatening. Tell your doctor immediately if you have any of the symptoms of inflammation. The signs and symptoms of potential inflammatory side effects of Yervoy are described under "POSSIBLE SIDE EFFECTS" in this leaflet.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning 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.

Driving and using machines

Do not drive or use machines after you have been given YERVOY unless you are sure that you are not affected.

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.

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.

HOW YERVOY IS 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) over a period of 90 minutes.

YERVOY is a concentrate solution for infusion. The amount of YERVOY you will be given will be calculated based on your body weight. Depending on your dose, some or all of the content of the YERVOY vial may be diluted with saline or glucose solution before use. More than one vial may be necessary to obtain the required dose.

Dosage and frequency of administration

The recommended dose is 3 mg of ipilimumab per kilogram of your body weight. You will be treated with YERVOY once every 3 weeks for a total of 4 doses, depending on your response to treatment.

You may need further treatment with YERVOY. Your doctor will discuss this with you.

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 stop using YERVOY

Stopping your treatment may stop the effect of the medicine. Do not stop treatment with YERVOY unless you have discussed this with your doctor.

If you have any further questions about your treatment or the use of this medicine, ask your doctor.

WHILE YOU ARE BEING TREATED WITH YERVOY

Things you must do

Tell your doctor immediately if you have any symptoms of inflammation in parts of your body. Tell any other doctors, dentists, 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.

Tell your doctor immediately if you develop symptoms of an allergic reaction.

These symptoms may be:

- 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.

POSSIBLE SIDE EFFECTS

Like all medicines, YERVOY can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

Be aware of important symptoms of inflammation

YERVOY acts 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.

It is important that you tell your doctor immediately if you have, or develop, any of the symptoms listed below.

Your doctor can then give you treatment to prevent more severe complications. Your doctor may decide to prescribe other medicines in order to reduce your symptoms, withhold the next dose of YERVOY, or stop your treatment with YERVOY altogether.

SIGNS AND SYMPTOMS OF INFLAMMATION

- **Bowel and stomach inflammation which can worsen to bleedings or bowel perforation**
 - diarrhoea (watery, loose or soft stools)
 - an increased number of bowel movements (an increase by two or more per day)
 - constipation
 - blood in your stools, or darker-coloured stools
 - pain or tenderness in your stomach area
- **Liver damage or hepatitis**
 - yellowing of your skin or the whites of your eyes (jaundice)
 - pain in your stomach area
 - excessive sleepiness
- **Skin rash or itching**
 - red or itchy rash
 - peeling skin
 - dry skin
- **Nerve damage**
 - muscle weakness or decreased strength
 - numbness or tingling in your hands or feet
 - loss of consciousness or difficulty waking up
- **Damage or inflammation of hormone producing glands**
 - headaches
 - blurry or double vision
 - fatigue
 - decreased sexual drive
 - behavioural changes
- **Eye inflammation**
 - redness in the eye
 - pain in the eye
 - vision changes or blurry vision

These 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 have blood tests during treatment.

Tell your doctor immediately if you have any symptoms or your symptoms get worse. Do not try to treat your symptoms with other medicines.

The following side effects have been reported in clinical trials:

Very common side effects (affects more than 1 user in 10):

- loss of appetite
- diarrhoea
- feeling sick (nausea) or being sick (vomiting)
- stomach pain
- itching, skin rash
- feeling tired or weak
- cough
- headache
- fever
- insomnia

Tell your doctor immediately if you get any of these side effects. Do not try to treat your symptoms with other medicines.

Common side effects (affects 1 to 10 users in 100):

- serious bacterial infection of the blood (sepsis)

- tumour pain
- underactive function of pituitary gland (hypopituitarism), the adrenal glands, or underactive function of the thyroid gland (hypothyroidism) which can cause tiredness or weight gain
- overactive function of the thyroid gland (hyperthyroidism), which can cause rapid heart rate, sweating and weight loss
- dehydration
- inflammation of the eye which causes pain and redness, blurred vision
- low blood pressure, temporary redness of the face and neck
- shortness of breath, bleeding in the stomach or intestine (gut), inflammation of the colon (large bowel), constipation
- weight loss
- abnormal function of the liver
- inflammation and redness of the skin, skin colour change in patches (vitiligo), hair loss or thinning
- excessive sweating at night
- pain in muscles and joints
- kidney function failure
- fever, shivering, lack of energy
- swelling, pain, reaction at site of injection
- confusion
- increase in alkaline phosphatase (an enzyme released by the liver)
- influenza-like illness

Tell your doctor immediately if you get any of these side effects. Do not try to treat your symptoms with other medicines.

Uncommon side effects (affects 1 to 10 users in 1,000):

- serious bacterial infection of the blood (sepsis, septic shock)
- urinary tract infection, kidney disease, kidney function failure
- inflammation of the stomach and intestines
- depression, lowered sex drive
- inflammation of blood vessels in the skin, hives (itchy, bumpy rash), painful skin lesions of the arms, legs and face
- muscle spasms, painful joints, muscle inflammation
- change or absence of menstrual periods
- pain in the eye, reduced vision, bleeding in the eye, a foreign body sensation in the eyes, inflammation of the eye muscle, swollen runny eyes
- irregular or abnormal heart beat
- extreme difficulty breathing, inflammation of the lungs, fluid in the lungs, hay fever
- disease of blood vessels, low blood pressure, feeling of intense heat with sweating and rapid heartbeat, weakness of the heart muscle, fluid around the heart
- damage to the nerves (causing pain, weakness and cramps), dizziness, brief involuntary muscle contraction, shaking, excessive accumulation of water in the brain, disease of nerves in the head, difficulty in speaking, difficulty in coordinating movements (ataxia)
- bowel perforation, stomach wall membrane inflammation, inflammation of the duodenum, of the bowel or of the pancreas, heartburn

- a group of metabolic complications occurring after cancer treatment
- liver failure, enlarged liver, inflammation of the liver, thyroid gland, kidney, pancreas or central nervous system, nodules of inflammatory cells in various organs of your body, immune-related effects of the inner surface lining of a particular organ, yellowing of the skin or eyes (jaundice)
- reaction related to infusion, multi-organ failure
- reduction of red blood cells
- multi organ inflammation
- decreased hearing
- change in hair colour
- mucosal inflammation
- infusion related reaction

Tell your doctor immediately if you get any of these side effects.

Do not try to treat your symptoms with other medicines.

Rare side effects (affects 1 to 10 users in 10,000):

- infection of the airways or of the upper respiratory tract
- infection around the brain or spinal cord
- allergic reaction (shock)
- decreased function of the adrenal glands caused by an underactive hypothalamus (part of the brain) or an overactive pituitary gland (a small gland at the base of the brain), defect in glands producing sex hormones
- antibodies against some of your own body cells causing damage to the thyroid gland or inflammation of the kidney or brain
- changes in mental health
- inflammation of the nerves (causing pain, weakness or paralysis in the extremities), drowsiness or lack of energy
- triad of symptoms (meningism): neck stiffness, intolerance of bright light and headache
- inflammation of the eye, swollen runny eyes, inflammation of the coloured part of the eye, swelling of the eye
- inflammation of the heart muscle, disease of the heart muscle, irregular heart beat
- restriction in blood supply of the extremities, inflammatory destruction of blood vessels, inflammatory disease of blood vessels (most commonly head arteries), poor blood circulation which makes toes and fingers numb or pale
- breathing failure caused by fluid in the lungs
- inflammatory disease of the intestines (causing abdominal pain, diarrhoea which may be bloody, vomiting or weight loss)
- peeling skin
- inflammation of muscles, causing pain or stiffness in hip and shoulder
- hearing disorder

Tell your doctor immediately if you get any of these side effects.

Do not try to treat your symptoms with other medicines.

Changes in test results

YERVOY may cause changes in the results of tests carried out by your doctor. These include:

- a variation in the number of red blood cells (which carry oxygen), of white blood cells (which are important in fighting infection) or of platelets (cells which help the blood to clot)
- an abnormal variation of hormones and liver enzyme levels in the blood
- a low blood level of sodium, of phosphate or of potassium
- blood or proteins in the urine
- an increased level of rheumatoid factor
- kidneys unable to remove acids from blood normally
- an abnormally high alkalinity of the blood and other body tissues
- presence of antibodies in the blood against some of your own cells

If any of the side effects listed in this leaflet appear or worsen, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Do not be alarmed by possible side effects.

You may not experience any of them.

Ask your doctor to answer any questions you may have.

FURTHER INFORMATION

What YERVOY contains

- The active substance is ipilimumab. Each vial contains either 50 mg or 200 mg of ipilimumab. Before dilution, each one mL of concentrate contains 5 mg of ipilimumab.
- The other ingredients are trometamol hydrochloride, sodium chloride, mannitol (E421), pentetic acid, polysorbate 80, sodium hydroxide, hydrochloric acid and water for injection.

What YERVOY looks like and contents of the pack

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.

Not all pack sizes may be marketed.

HOW TO STORE YERVOY

It is unlikely that you will be asked to store YERVOY yourself. It will be stored in the hospital or clinic where it is given to you.

Keep YERVOY out of the reach and sight of children.

Do not use YERVOY after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

- Store in a refrigerator (2°C to 8°C).
- Do not freeze.
- Store in the original package in order to protect from light.

From a microbiological point of view, once opened, the medicinal product should be infused or diluted and infused immediately. The chemical and physical in use stability of the undiluted or diluted infusion solution has been demonstrated for 24 hours at room temperature (20°C to 25°C) or when refrigerated (2°C to 8°C). Other in-use storage time and conditions are the responsibility of the user.

Manufacturer

YERVOY is manufactured in the United States of America and distributed in Australia by:

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave
Victoria 3170, Australia

Registration Numbers

- 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.

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