

MEDICATION GUIDE

YERVOY® (yur-voi) (ipilimumab) injection

Read this Medication Guide before you start receiving YERVOY and before each infusion. There may be new information. If your healthcare provider prescribes YERVOY in combination with nivolumab, also read the Medication Guide that comes with nivolumab. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about YERVOY?

YERVOY is a medicine that may treat certain cancers by working with your immune system. YERVOY can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You may have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when YERVOY is used in combination with nivolumab.

Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

Intestinal problems.

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdominal) pain or tenderness

Liver problems.

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach-area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Skin problems.

- rash
- itching
- skin blistering or peeling
- painful sores in mouth or nose, throat, or genital area

Hormone gland problems.

- headache that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Lung problems.

- new or worsening cough
- shortness of breath
- chest pain

Kidney problems.

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite

Eye problems.

- blurry vision, double vision, or other vision problems
- eye pain or redness

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with YERVOY. Call or see your healthcare provider right away for any new or worsening signs or symptoms.

- Chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with YERVOY. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with YERVOY if you have severe side effects.

What is YERVOY?

YERVOY is a prescription medicine used:

- **to treat a kind of skin cancer called melanoma.**

- YERVOY may be used alone or in combination with nivolumab in adults and children 12 years of age and older when melanoma has spread or cannot be removed by surgery.
- YERVOY may be used alone in adults to help prevent melanoma from coming back after it and lymph nodes that contain cancer have been removed by surgery.
- **in adults with kidney cancer (renal cell carcinoma).** YERVOY may be used in combination with nivolumab in certain people when their cancer has spread.
- **in adults and children 12 years of age and older, with a type of colon or rectal cancer (colorectal cancer).**
 - YERVOY may be used in combination with nivolumab when your colon or rectal cancer:
 - cannot be removed with surgery, or has spread, **and**
 - is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).
- **in adults with liver cancer (hepatocellular carcinoma).**
 - YERVOY may be used in combination with nivolumab as your first treatment when your liver cancer:
 - cannot be removed by surgery, **or**
 - has spread.
 - YERVOY may be used in combination with nivolumab when your liver cancer:
 - cannot be removed by surgery, **or**
 - has spread, **and**
 - you have received prior treatment with sorafenib.
- **in adults with a type of lung cancer called non-small cell lung cancer (NSCLC).**
 - YERVOY may be used in combination with nivolumab as your first treatment for NSCLC:
 - when your lung cancer has spread to other parts of your body (metastatic), **and**
 - your tumors are positive for PD-L1, but do not have an abnormal EGFR or ALK gene.
 - YERVOY may be used in combination with nivolumab and 2 cycles of chemotherapy that contains platinum and another chemotherapy medicine, as the first treatment of your NSCLC when your lung cancer:
 - has spread or grown, or comes back, **and**
 - your tumor does not have an abnormal EGFR or ALK gene.
- **in adults with a type of cancer that affects the lining of the lungs and chest wall called malignant pleural mesothelioma.**
 - YERVOY may be used in combination with nivolumab as your first treatment for malignant pleural mesothelioma that cannot be removed by surgery.
- **in adults with cancer of the tube that connects your throat to your stomach (esophageal cancer).**
 - YERVOY may be used in combination with nivolumab as your first treatment when your esophageal cancer:
 - is a type called squamous cell carcinoma, **and**
 - cannot be removed with surgery (advanced), or has spread to the other parts of the body (metastatic), **and**
 - your tumors are positive for PD-L1.

It is not known if YERVOY is safe and effective in children younger than 12 years of age with melanoma that has spread or cannot be removed by surgery, or with MSI-H or dMMR metastatic colorectal cancer.

It is not known if YERVOY is safe and effective in children for the treatment of any other cancers.

Before you receive YERVOY, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as ulcerative colitis, Crohn's disease, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. YERVOY can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with YERVOY.
- You should use an effective method of birth control during treatment and for 3 months after your last dose of YERVOY. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with YERVOY. You or your healthcare provider should contact Bristol-Myers Squibb at 1-844-593-7869 as soon as you become aware of a pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if YERVOY passes into your breast milk. Do not breastfeed during treatment and for 3 months after your last dose of YERVOY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive YERVOY?

- Your healthcare provider will give you YERVOY into your vein through an intravenous (IV) line.
- YERVOY is usually given over **30** minutes.
- If you are receiving YERVOY as treatment for melanoma that has been removed by surgery to help prevent it from coming back, YERVOY will be given over **30** minutes.

- In combination with nivolumab, YERVOY is usually given every 3 weeks for up to 4 doses. After that, nivolumab alone is usually given every 2 or 4 weeks.
- For NSCLC that has spread to other parts of your body, YERVOY is given every 6 weeks and nivolumab is given every 3 weeks for up to 2 years. Your healthcare provider will determine if you will also need to receive chemotherapy every 3 weeks for 2 cycles.
- For malignant pleural mesothelioma that cannot be removed by surgery, YERVOY is given every 6 weeks and nivolumab is given every 3 weeks for up to 2 years.
- When YERVOY is used in combination with nivolumab for esophageal squamous cell carcinoma (ESCC), YERVOY is given every 6 weeks and nivolumab is given every 2 or 3 weeks for up to 2 years.
- Your healthcare provider will decide how many treatments you will need.
- Your healthcare provider will do blood tests before starting and during treatment with YERVOY.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of YERVOY?

YERVOY can cause serious side effects, including:

- **See “What is the most important information I should know about YERVOY?”**
- **Severe infusion-related reactions.** Tell your healthcare provider or nurse right away if you get these symptoms during an infusion of YERVOY:
 - chills or shaking
 - itching or rash
 - flushing
 - shortness of breath or wheezing
 - dizziness
 - feel like passing out
 - fever
 - back or neck pain
- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with YERVOY. Your healthcare provider will monitor you for these complications.

The most common side effects of YERVOY when used alone include:

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| • feeling tired | • headache |
| • diarrhea | • weight loss |
| • nausea | • fever |
| • itching | • decreased appetite |
| • rash | • difficulty falling or staying asleep |
| • vomiting | |

The most common side effects of YERVOY when used in combination with nivolumab include:

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| • feeling tired | • vomiting |
| • diarrhea | • stomach-area (abdominal) pain |
| • rash | • shortness of breath |
| • itching | • upper respiratory tract infection |
| • nausea | • headache |
| • pain in muscles, bones, and joints | • low thyroid hormone levels (hypothyroidism) |
| • fever | • constipation |
| • cough | • decreased weight |
| • decreased appetite | • dizziness |

The most common side effects of YERVOY when used in combination with nivolumab and chemotherapy include:

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| • feeling tired | • rash |
| • pain in muscles, bones, and joints | • decreased appetite |
| • nausea | • constipation |
| • diarrhea | • itching |

These are not all of the possible side effects of YERVOY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of YERVOY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about YERVOY, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about YERVOY that is written for health professionals.

What are the ingredients of YERVOY?

Active ingredient: ipilimumab

Inactive ingredients: diethylene triamine pentaacetic acid (DTPA), mannitol, polysorbate 80 (vegetable origin), sodium chloride, tris hydrochloride, and Water for Injection

Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
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For more information, call 1-800-321-1335

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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