

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 can cause serious side effects in many parts of your body which can lead to death. These problems may happen anytime during treatment with YERVOY or after you have completed treatment. Some of these problems may happen more often when YERVOY is used in combination with nivolumab.

Call your healthcare provider right away if you develop any of these signs or symptoms or they get worse. Do not try to treat symptoms yourself.

Intestinal problems (colitis) that can cause tears or holes (perforation) in the intestines. Signs and symptoms of colitis may include:

- diarrhea (loose stools) or more bowel movements than usual
- mucus or blood in your stools
- dark, tarry, sticky stools
- stomach pain (abdominal pain) or tenderness
- you may or may not have fever

Liver problems (hepatitis) that can lead to liver failure. Signs and symptoms of hepatitis may include:

- yellowing of your skin or the whites of your eyes
- dark urine (tea colored)
- nausea or vomiting
- pain on the right side of your stomach
- bleeding or bruise more easily than normal
- decreased energy

Skin problems that can lead to severe skin reaction. Signs and symptoms of severe skin reactions may include:

- skin rash with or without itching
- sores in your mouth
- your skin blisters or peels

Nerve problems that can lead to paralysis. Symptoms of nerve problems may include:

- unusual weakness of legs, arms, or face
- numbness or tingling in hands or feet

Hormone gland problems (especially the pituitary, adrenal, and thyroid glands). Signs and symptoms that your glands are not working properly may include:

- persistent or unusual headaches
- unusual sluggishness
- feeling cold all the time
- weight gain
- changes in mood or behavior such as decreased sex drive, irritability, or forgetfulness
- dizziness or fainting

Lung problems (pneumonitis). Symptoms of pneumonitis may include:

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

Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include:

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

Inflammation of the brain (encephalitis). Signs and symptoms of encephalitis may include:

- headache
- fever
- tiredness or weakness
- confusion
- memory problems
- sleepiness
- seeing or hearing things that are not really there (hallucinations)
- seizures
- stiff neck

Eye problems. Symptoms may include:

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

Getting medical treatment right away may keep the problem from becoming more serious.

Your healthcare provider will check you for these problems during treatment with YERVOY. Your healthcare provider may treat you with corticosteroid medicines. Your healthcare provider may 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:
 - in adults and children 12 years of age and older when melanoma has spread or cannot be removed by surgery
 - to help prevent melanoma from coming back after it and lymph nodes that contain cancer have been removed by surgery
- **in people 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 in combination with nivolumab may be used when your colon or rectal cancer:
 - has spread to other parts of the body (metastatic).
 - is microsatellite stability-high (MSI-H) or mismatch repair deficient (dMMR), **and**
 - You have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.
- **in people with liver cancer (hepatocellular carcinoma).**
 - YERVOY may be used in combination with nivolumab if you have previously received 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.

It is not known if YERVOY is safe and effective in children younger than 12 years of age.

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

- have immune system problems (autoimmune disease), such as ulcerative colitis, Crohn's disease, lupus, or sarcoidosis
- have had an organ transplant
- have liver problems
- are pregnant or plan to become pregnant. YERVOY can harm your unborn baby.
 - Females who are able to become pregnant should use effective birth control during treatment with YERVOY and for 3 months after the last dose of YERVOY.
 - If you become pregnant or think you are pregnant, tell your healthcare provider right away. You or your healthcare provider should contact Bristol-Myers Squibb at 1-800-721-5072 as soon as you become aware of the pregnancy.
 - **Pregnancy Safety Surveillance Study: Females** who become pregnant during treatment with YERVOY are encouraged to enroll in a Pregnancy Safety Surveillance Study. The purpose of this study is to collect information about the health of you and your baby. You or your healthcare provider can enroll you in the Pregnancy Safety Surveillance Study by calling 1-844-593-7869.
- are breastfeeding or plan to breastfeed. It is not known if YERVOY passes into your breast milk.
 - **Do not** breastfeed during treatment with YERVOY and for 3 months after the 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?

- YERVOY alone is given to you into your vein through an intravenous (IV) line over 90 minutes.
- When YERVOY is used in combination with nivolumab, nivolumab is given to you into your vein through an IV line over 30 minutes. Then YERVOY is also given through an IV over 30 minutes on the same day.

- YERVOY in combination with nivolumab is usually given every 3 weeks for 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 either every 2 or 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.
- 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.
- It is important for you to keep all appointments with your healthcare provider. Call your healthcare provider if you miss an appointment. There may be special instructions for you.

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 reactions. Tell your doctor or nurse right away if you get these symptoms during an infusion of YERVOY:**
 - chills or shaking
 - itching or rash
 - flushing
 - difficulty breathing
 - dizziness
 - fever
 - feeling like passing out

Graft-versus-host disease, a complication that can happen after receiving a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic), may be severe, and can lead to death, if you receive YERVOY either before or after transplant. Your healthcare provider will monitor you for the following signs and symptoms: skin rash, liver inflammation, stomach-area (abdominal) pain, and diarrhea.

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

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

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

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

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

- feeling tired
- pain in muscles, bones, and joints
- nausea
- diarrhea
- rash
- decreased appetite
- constipation
- 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. You can ask your healthcare provider or pharmacist for information about YERVOY that is written for healthcare professionals.

What are the ingredients of YERVOY?**Active ingredient:** ipilimumab**Inactive ingredients:** diethylene triamine pentaacetic acid (DTPA), mannitol, polysorbate 80, sodium chloride, tris hydrochloride, and Water for Injection

Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

For more information, call 1-800-321-1335

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

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