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.

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
- blood in your stools or dark, tarry, sticky stools
- stomach pain (abdominal pain) or tenderness

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

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

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:
- when your 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.
It is not known if YERVOY is safe and effective in children less than 18 years of age.

What should I tell my healthcare provider before receiving YERVOY?
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.
  o 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.
- are breastfeeding or plan to breastfeed.
  o It is not known if YERVOY passes into your breast milk.
  o 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 all prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list to show your healthcare providers and pharmacists each time you get a new medicine.

You should not start a new medicine before you talk with the healthcare provider who prescribes you YERVOY.

How will I receive YERVOY?
- YERVOY is given to you into your vein through an intravenous (IV) line over 90 minutes.
- 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. See "What is the most important information I should know about YERVOY?"

The most common side effects of YERVOY include:

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

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects of YERVOY. For more information, ask your healthcare provider.

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

You may also report side effects to Bristol-Myers Squibb at 1-800-721-5072.

General information about the safe and effective use of YERVOY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about YERVOY. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about YERVOY that is written for healthcare professionals. For more information, call 1-800-321-1335.

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, USP

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

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This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 10/2015