



EUROPEAN MEDICINES AGENCY  
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## Yervoy (*ipilimumab*)

An overview of Yervoy and why it is authorised in the EU

### What is Yervoy and what is it used for?

Yervoy is a cancer medicine used to treat the following:

- melanoma, a type of skin cancer;
- renal cell carcinoma (a kidney cancer) in adults who are at moderate or high risk of their cancer getting worse;
- a lung cancer called non-small cell lung cancer (NSCLC);
- malignant pleural mesothelioma (a cancer of the lining of the lungs);
- a kind of cancer of the colon or rectum (lower part of the gut) that is described as microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR);
- squamous oesophageal cancer (cancer of the oesophagus, the passage from the mouth to the stomach);
- hepatocellular carcinoma (HCC), a type of liver cancer, in previously untreated patients.

The medicine is used in adults; for melanoma it is also used in adolescents from 12 years of age.

Yervoy is mainly used when the cancer is advanced, unresectable (cannot be removed by surgery) or metastatic (has spread to other parts of the body), and has not been treated before. Yervoy is usually used in combination with nivolumab (another cancer medicine), but it can also be used on its own for melanoma. For NSCLC, Yervoy is given in combination with both nivolumab and another cancer medicine.

For certain cancers, tests may be needed before treatment with Yervoy in combination with nivolumab to measure the level of a protein called PD-L1 or to check the patient has an MSI-H or dMMR tumour. This is because nivolumab works on cancer cells that produce PD-L1 and on cancers determined to be MSI-H or dMMR.

Yervoy contains the active substance ipilimumab.

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## How is Yervoy used?

Yervoy can only be obtained with a prescription, and treatment should be started and supervised by a doctor experienced in treating cancer.

Yervoy is given by infusion (drip) into a vein. The dose and how often it is given depends on the condition it is being used for and on the patient's weight.

The doctor may delay doses if certain side effects occur or stop treatment altogether if side effects are severe.

For more information about using Yervoy, see the package leaflet or contact a doctor or pharmacist.

## How does Yervoy work?

The active substance in Yervoy, ipilimumab, is a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to attach to a specific target in the body.

Ipilimumab increases the number and the activity of a type of white blood cells called T cells which form part of the immune system and can kill cancer cells. It acts on T cells by attaching to and blocking the activity of CTLA-4, a protein that controls the activity of T cells.

## What benefits of Yervoy have been shown in studies?

### Advanced melanoma

Several studies have shown that Yervoy is effective in prolonging the lives of patients with advanced melanoma.

In a study involving 676 adults in whom previous treatment for advanced melanoma had not worked or had stopped working, overall survival with Yervoy alone or with Yervoy combined with an experimental medicine called 'gp100' was about 10 months, compared with 6 months in patients receiving gp100 alone.

In a study involving 502 adults whose advanced melanoma had not been treated previously, patients treated with high-dose Yervoy and dacarbazine lived for 11 months on average, compared with 9 months for those given placebo (a dummy treatment) plus dacarbazine. However, about one-third of the patients could not complete Yervoy treatment due to side effects.

Finally, two studies found the combination of Yervoy and nivolumab effective for treating advanced melanoma in adults who had not been treated previously, and whose cancer produced a protein called PD-L1. In the first of these studies involving 945 adults, patients treated with Yervoy and nivolumab lived for 11.7 months on average without their disease getting worse compared with 6.9 months for those treated with nivolumab alone and 2.9 months for those treated with Yervoy alone. In the second study involving 142 adults, the disease was controlled in 56% of patients receiving Yervoy and nivolumab compared with 9% of patients receiving Yervoy alone.

In two small studies involving a total of 30 adolescents aged 12 to 18 years with advanced melanoma, treatment with Yervoy produced similar levels of medicine in blood as in adults. In addition, melanoma in adolescents is similar to the disease in adults and Yervoy behaves in a similar way in adults and adolescents. Therefore, the effects of Yervoy in adolescents are expected to be similar to those in adults. Because the medicine has been studied in very few adolescents, there is uncertainty about the medicine's side effects. Therefore, all adolescents treated with Yervoy will be monitored closely.

### **Advanced renal cell carcinoma**

One main study involving 1,096 adults with previously untreated advanced renal cell carcinoma compared treatment with Yervoy and nivolumab versus treatment with another cancer medicine for renal cell carcinoma, sunitinib. The results showed that in patients at moderate or high risk of their cancer getting worse, patients given the combination lived longer than those given sunitinib. After 24 months, around 67% of patients given the combination were alive compared with 53% in the sunitinib group. In addition, 42% of patients (177 out of 423) responded to the treatment with the combination compared with 27% (112 out of 416) of those receiving sunitinib. The time patients lived before their disease got worse was 11.6 months with the combination compared with 8.4 months with sunitinib.

### **Metastatic NSCLC**

One main study in 719 adults who had not previously been treated showed that patients given Yervoy in combination with nivolumab and another cancer medicine lived on average for 15.6 months after starting treatment compared with 10.9 months in patients given chemotherapy.

### **Malignant pleural mesothelioma**

A main study involving 605 patients with malignant pleural mesothelioma that could not be removed by surgery looked at how long patients lived when they received Yervoy with nivolumab or when they received chemotherapy. In this study, patients who received Yervoy and nivolumab lived on average for 18 months while patients who had chemotherapy lived for an average of 14 months.

### **Cancer of the colon or rectum**

A main study involving 119 patients with MSI-H or dMMR colon or rectal cancer examined the effect of treatment with a combination of Yervoy and nivolumab. Around 65% of patients who had the combination responded to treatment and had a reduction in tumour size.

A second main study involved 303 patients with metastatic MSI-H or dMMR colon or rectal cancer who had not been previously treated for their metastatic disease and whose cancer could not be removed by surgery. Patients either received Yervoy given with nivolumab for up to 4 doses, followed by nivolumab alone, or they received chemotherapy. Those who received chemotherapy lived for an average of 5.9 months before the disease got worse; for patients who received Yervoy plus nivolumab, the period could not be calculated because the disease had not worsened in many patients during an average follow-up of 32 months.

### **Advanced squamous oesophageal cancer**

A main study found that Yervoy in combination with nivolumab prolonged the lives of people with previously untreated squamous oesophageal cancer that could not be removed by surgery, had come back or had spread. The study involved 649 adults who either received Yervoy plus nivolumab or chemotherapy. Patients whose cancer produced PD-L1 protein and who were treated with Yervoy plus nivolumab lived on average for 13.7 months compared with 9.1 months for those treated with chemotherapy. There was no difference between the two treatments in the time patients lived without their disease worsening.

### **Unresectable or advanced HCC**

A main study involved 668 adults with previously untreated HCC that cannot be removed by surgery or is advanced. Yervoy in combination with nivolumab was compared with another cancer treatment chosen by the doctor (either sorafenib or lenvatinib). Patients who received Yervoy with nivolumab lived longer: for about 24 months on average compared with about 21 months for those given another treatment. Additionally, about 36% of patients had either shrinkage of the tumour or no sign of cancer

after treatment with Opdivo and ipilimumab, compared with about 13% for those given another treatment.

## **What are the risks associated with Yervoy?**

For the full list of side effects and restrictions with Yervoy, see the package leaflet.

The most common side effects with Yervoy on its own (which may affect more than 1 in 10 people) include rash, itching, tiredness, diarrhoea, nausea (feeling sick), vomiting, decreased appetite and abdominal (belly) pain. Reactions to the infusion, which can be severe, may affect up to 1 in 100 people; these include fever, chills, flushing and shortness of breath.

Yervoy is also commonly associated with side effects related to the activity of the immune system on body organs. Most will go away with appropriate treatment or upon stopping Yervoy.

Additional side effects may occur when Yervoy is used with other cancer medicines.

## **Why is Yervoy authorised in the EU?**

The European Medicines Agency noted that Yervoy improves survival in melanoma, a condition where overall survival rates are low.

Yervoy has also been shown to benefit patients with advanced renal cell carcinoma, NSCLC, malignant pleural mesothelioma, cancer of the colon or rectum, squamous oesophageal cancer and hepatocellular carcinoma.

The most frequent side effects of the medicine are mild to moderate in severity and considered manageable with appropriate measures. Because studies with Yervoy in the treatment of melanoma included very few adolescents, the company has committed to collecting information on side effects, including any effects on growth and sexual maturation.

The Agency therefore decided that Yervoy's benefits are greater than its risks and it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Yervoy?**

The company that markets Yervoy must ensure that patients treated with Yervoy are given a patient card with safety information on the medicine, including the side effects resulting from excessive activity of the immune system and infusion-related reactions.

As it is not clear how much Yervoy contributes to the benefits when given in combination with nivolumab in patients with advanced renal cell carcinoma, the company must conduct a study to determine the precise contribution of Yervoy and if the risks associated with it can be further minimised.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Yervoy have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Yervoy are continuously monitored. Side effects reported with Yervoy are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Yervoy**

Yervoy received a marketing authorisation valid throughout the EU on 13 July 2011.

Further information on Yervoy can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/yervoy](https://ema.europa.eu/medicines/human/EPAR/yervoy).

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