

Your guide to YERVOY™

Patient Information Brochure

ADR forms can be downloaded from www.medicinesauthority/adportal and sent by post to 203, Level 3 Rue D'Argens Gzira or by email to postlicensing.medicinesauthority@gov.mt

YERVOY™ is subject to additional monitoring to quickly identify new safety information. You can help by reporting any side effects you may get. This educational material is mandatory as a condition of the marketing authorization in order to further minimize important selected risks.



Bristol-Myers Squibb

Introduction

You have been diagnosed with advanced melanoma and prescribed YERVOY™ (ipilimumab).

This booklet is from the team responsible for your care to help you identify any side effects that you may get on YERVOY™.

It is important to tell your doctor, nurse or clinic immediately about any symptoms you may get.



Glue
Alert Card
here

Contact us on this number

Name of Physician:

Phone number:

Name of Nurse:

Phone number:

About YERVOY™

- **YERVOY™ is a medicine used to treat advanced melanoma** (a type of skin cancer) in adults.
- **It works in a different way to traditional cancer treatments** (e.g. chemotherapy), by helping your immune system to attack and destroy cancer cells.¹

What to expect with your treatment

Before the treatment, we will check:

- ✓ if you take corticosteroids or other treatments that affect the immune system
- ✓ if you take any medicines that stop your blood from clotting (anticoagulants)
- ✓ liver function tests (LFTs)
- ✓ thyroid function tests
- ✓ if you have an autoimmune disease (a condition where the body attacks its own cells)
- ✓ your general physical condition and determine whether you are suitable for treatment
- ✓ if you have or have ever had a chronic viral infection of the liver, including:
 - ✓ hepatitis B (HBV)
 - ✓ hepatitis C (HCV)
- ✓ if you have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)

Please also tell us if you are pregnant, breast-feeding or planning to become pregnant.¹

What to expect with your treatment (cont'd)

Administration

Your treatment will be given to you as an infusion (a drip) intravenously (into a vein). The infusion will take an hour and a half to complete. The amount of YERVOY™ (ipilimumab) you will receive depends on your body weight.¹

**In total, you will receive
4 doses of YERVOY™, 1 every 3 weeks.¹**

YERVOY™'s effects may take a while to show up

You may notice the appearance of new lesions or growth of existing lesions on your skin, which can be expected during your treatment. We will continue giving you your treatment for a total of 4 doses, depending on your tolerance to the treatment.

It is important that you make every effort to receive your dose as scheduled.

Contact us immediately if you are unable to keep an appointment.

We will check how your tumour has responded to treatment only after you have completed the entire course.¹

Possible side effects

All medicines can cause side effects, although not everybody gets them. Side effects should always be taken seriously and reported immediately to us, as prompt treatment is the best way to ensure they will not worsen and lead to death. If side effects occur, they usually do so in the first 12 weeks of treatment. However, side effects are sometimes delayed, and may develop weeks or months after the last dose.¹

If you develop any side effects with your treatment or your symptoms worsen, tell us immediately. It is also important that you do not try to treat your symptoms on your own.¹

The main side effects of your treatment

The most common side effects are related to the way in which the medicine fights the skin cancer by boosting the immune system. These side effects are related to the immune mechanism of action of the medicine and are different from the side effects experienced with other types of cancer treatment.²

It is important to tell us immediately if you have, or develop, any symptoms such as those listed below, even if they don't seem serious or you're not sure.¹

Signs or symptoms	Side effect or affected organ
<ul style="list-style-type: none">• diarrhoea (watery, loose or soft stools), vomiting or nausea• an increased number of bowel movements than usual• blood in your stools, or darker-coloured stools• pain or tenderness in your stomach area, fever	Inflammation of the intestines (colitis) which can worsen to bleedings or bowel perforation
<ul style="list-style-type: none">• eye or skin yellowing (jaundice)• pain on the right side of your stomach area• tiredness• dark urine	Inflammation of the liver (hepatitis) that can lead to liver failure
<ul style="list-style-type: none">• skin rash with or without itching• blisters and/or peeling of the skin, mouth sores• dry skin	Inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis)
<ul style="list-style-type: none">• muscle weakness• numbness or tingling in your hands or feet• dizziness, loss of consciousness or difficulty waking up	Inflammation of the nerves that can lead to paralysis
<ul style="list-style-type: none">• headaches• blurry or double vision• tiredness• decreased sexual drive• behavioural changes (e.g. being irritable or forgetful)	Inflammation of the hormone-producing glands (especially the pituitary, adrenal and thyroid glands) that may affect how these glands work
<ul style="list-style-type: none">• redness in the eye• pain in the eye• vision problems or blurry vision	Inflammation of the eyes

Under no circumstances should you attempt to treat these symptoms yourself without seeking appropriate medical assistance.¹

Monitoring your symptoms of potential side effects

Why it is important to monitor your symptoms

It is critical that any side effects associated with your treatment be recognised early as this will enable us to treat them promptly and may prevent symptoms from becoming worse.¹

Do not delay, as some side effects quickly worsen if not treated, whereas most rapidly improve or disappear if treated early.

How your symptoms will be treated

The vast majority of symptoms related to your treatment resolve following appropriate medical care, allowing you to return to your normal activities.²

You may be prescribed corticosteroids if you experience moderate or severe symptoms. Sometimes, we may decide to withhold a dose in such cases; however, we will decide when you can continue your treatment.² It will only need to be discontinued if your symptoms are severe.¹ Remember, early treatment of side effects reduces the likelihood that treatment will need to be temporarily or permanently stopped, allowing you to get the maximum benefit from YERVOY™.²

Please contact us immediately if you feel unwell while you are on treatment.

What to do if symptoms occur whilst you are away from home

If symptoms occur whilst you are travelling, do not hesitate to go to the nearest hospital immediately. You should inform hospital staff of your treatment. It is important that you carry our contact details with you at all times in case you or another physician need to contact us urgently. **If the YERVOY™ Alert Card is not attached to this brochure, ask us to provide you with one.** Always carry your Alert Card with you and present it should you have to see another physician whilst on holiday for example, or in the rare event that we are unreachable.

**Always carry your Alert Card with you.
Show it to any medical staff who treat you for any reason at all.**

Follow-up

During the first 12 weeks of your treatment, you will have regular appointments with us to receive your infusions and for blood tests to check that you are tolerating the medicine. You should make every effort to keep your appointments.¹

Tell us immediately if you experience any side effects.

The beneficial effects of YERVOY™ are generally not seen right after initiation and may differ from patient to patient. This is due to the way in which the medicine works. Indeed, tumours occasionally grow or even appear during the time the medicine takes to trigger the immune system to attack the tumour. As a result, you should receive the entire course of treatment, depending on your tolerance, before we check how you have responded.¹

Please consult us if you have any questions concerning the beneficial effects of YERVOY™ treatment.

Special precautions

- Pay particular attention to your bowel movements, particularly if you experience diarrhoea.¹
- Do not take any other medicines during your treatment without talking to your doctor first.¹
- Side effects can occur within one week to several months after starting treatment. If you experience any symptoms, contact us immediately.¹
- Feeling tired or weak is a very common side effect which may also impair your ability to drive and use machines. You should not drive or use machines if you feel tired or weak.¹

1. YERVOY™ Package Leaflet.
2. YERVOY™ Summary of Product Characteristics.

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Where to find further information

For more information, consult the YERVOY™ Package Leaflet including Information for the User at www.ema.europa.eu



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