Your guide to YERVOY® (ipilimumab)

Patient Information Guide

YERVOY® (ipilimumab) contains the active substance ipilimumab, a protein which helps your immune system to attack and destroy cancer cells by your immune cells.

This guide has been designed to help you to identify any side effects that you may experience while you are on ipilimumab treatment.

You have been prescribed ipilimumab in order to treat advanced melanoma (a type of skin cancer) in adults.

- ipilimumab can cause serious side effects in various parts of the body that need to be addressed immediately, regardless of their severity.
- Symptoms may include diarrhoea, eye or skin yellowing, skin rash with or without itching, blurry vision, pain in the eye, muscle weakness, numbness or tingling in legs, arms, or face, or headache.
- Before receiving the treatment, inform your doctor of all known medical conditions.
- Call your doctor immediately if you develop any of these the symptoms mentioned in this card, or any other symptoms, or if the symptoms persist or get worse.
- Always carry the Patient Alert Card with you and show it to any doctor you consult.
- Additional information concerning ipilimumab is available in the package leaflet.

Bristol-Myers Squibb

Introduction

This guide includes a Patient Alert Card. Always carry your Patient Alert Card with you and show it to any doctor you consult (for example, if your regular doctor is unavailable or you are travelling).

Glue
Alert Card
here

Contact us on this number

Name of Physician:

Phone number:

Name of Nurse:

Phone number:

The main side effects of your treatment

It is important to tell your doctor immediately if you have, or develop, any side effects such as those listed below.

Early treatment of side effects reduces the likelihood that ipilimumab treatment will need to be temporarily or permanently stopped, allowing you to get the maximum benefit from treatment.

Tell your doctor also if side effects worsen, even if they do not seem serious or you are not sure.[1]

If side effects occur, they usually do so in the first 12 weeks of treatment. However, side effects may be delayed, and develop weeks or months after the last dose[1].

BOWEL AND STOMACH[1] • diarrhoea (watery, loose or soft stools), bloody or dark colored stools • more frequent bowel movements than usual • pain or tenderness in your stomach or abdomen area, nausea, vomiting	GENERAL[1] • fever, headache, tiredness • bleeding • behavioural changes (e.g. less sex drive, being irritable or forgetful)
LIVER[1] • eye or skin yellowing (jaundice) • pain on the right side of your stomach area • tiredness • dark urine	NERVES[1] • muscle weakness • numbness or tingling in legs, arms, or face • dizziness, loss of consciousness or difficulty waking up
SKIN[1] • skin rash with or without itching • blisters and/or peeling of the skin, mouth sores • dry skin	EYE[1] • redness in the eye • pain in the eye • vision problems or blurry vision

- **Under no circumstances should you attempt to treat these symptoms yourself. You should seek medical assistance.**
- **Always take your Patient Alert Card with you and show it to any doctor you consult (for example, if your regular doctor is unavailable or you are travelling).**

What to expect with your treatment

Before the treatment, your doctor 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 to 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 your doctor if you are pregnant, breast-feeding or planning to become pregnant.[1]

1. YERVOY® package leaflet

Where to find further information

For more information, consult the YERVOY® Package Leaflet including Information for the User at www.ema.europa.eu or call Medical Information at 00356 2397 6 505

Any suspected adverse events should be reported to Medicines Authority. ADR report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and sent to postlicensing.medicinesauthority@gov.mt or sent to Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta.

731MT16NP07534-01 Approval date: xx-Nov-2016