W Bristol Myers Squibb"

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June 2020

The national Phaemacovigiance and Drug safety Center: Kr. https://ace.sfda.gov.sa Email: npc.drug@sfda.gov.sa Toll free number: 8002490000

Bristol Myers Squibb, Saudi Arabia: 0177 AP8 008: lls or or call: 800 844 7710

For reporting any suspected adverse reactions via the national reporting system :

OPDIVO® (nivolumab)

Patient Alert Card

1506AE2005376-03

June 2020

Bristol Myers Squibb

OPDIVO® (nivolumab) Important Information for Patients

Please carry this card with you at all times to inform healthcare professionals that you are receiving treatment with OPDIVO® or OPDIVO® in combination with YERVOY® (ipilimumab).



If you have any signs or symptoms, tell your doctor right away.



IMPORTANT

OPDIVO® treatment may increase the risk of serious or even life-threatening immune-related side effects, which may affect different parts of the body. Signs and symptoms to look out for include the following, though these are not the only ones:

• General:

Changes in mood or behavior (e.g., decreased sex drive, irritability, forgetfulness, depression), confusion, feeling unwell, fever, headaches, increased or decreased appetite, nausea or vomiting, seizures (fits), swollen lymph nodes, excessive thirst, tiredness, weight loss or gain, tingling and/or numbness.

• Eves:

Eyesight changes (e.g., blurry vision, other vision problems), eye redness or pain, yellowing of the whites of your eyes.

• Skin:

Skin dryness, itching, rash, blistering/peeling, or yellowing (jaundice), raised skin lumps/bumps, severe skin reactions.

Muscles and bones:

Difficulty walking, muscle or joint pains, muscle weakness, stiffness.

Mouth, nose and throat:

Ulcers in the mouth or other mucous membranes (e.g., nose, eyelids).

• Chest:

Chest pain, breathing difficulties, cough, irregular heartbeat, palpitations (being more aware of heartbeat than normal).

Stomach and bowel (gut):

Dark, tarry, or sticky stools, blood or mucous in your stools, diarrhea, pain or tenderness in your stomach or abdominal area.

Kidneys and bladder:

Decreased or increased amount of urine, darker urine.



IMPORTANT

- Tell your doctor of any previous medical conditions, including if you have had a stem cell transplant that uses donor stem cells (allogeneic).
- Early assessment and management of side effects by your doctor reduces the likelihood that treatment with OPDIVO® or OPDIVO® in combination with YERVOY® will need to be temporarily or permanently stopped.
- Signs and symptoms that may appear mild can quickly worsen if left untreated.
- DO NOT try to treat these symptoms yourself.
- Signs and symptoms may be delayed and may occur weeks to months after your last injection.

For more information, read the OPDIVO® Local leaflet which can be found in the product pack as appropriate and Patient Information Guide.

My Doctor's Contact Information (who prescribed OPDIVO® or OPDIVO® in combination with YERVOY®) Name of Doctor: Office Phone: After-Hours Phone: **My Contact Information** My Name and Phone: Emergency Contact (name and phone):



- This patient is treated with OPDIVO® or OPDIVO® in combination with YERVOY®.
- Immune-related adverse reactions (irARs) may appear at any time during treatment or months after its discontinuation.
- Early diagnosis and appropriate management are essential to minimize life-threatening complications.
- Consultation with an Oncologist or other medical specialist may be helpful for management of organ-specific irARs.
- Healthcare professionals should refer to the OPDIVO® Prescribing Information which can be found in the product pack.



The healthcare professional treating this patient with OPDIVO® or OPDIVO® in combination with YERVOY® should complete the 'My Doctor's Contact Information' section of this Patient Alert Card.

June 2020