יולי 2019

**Yervoy (Ipilimumab) 5 mg/ml**

**Concentrate for solution for infusion**

רופא/ה ,רוקח/ת יקר/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר **יירבוי** (איפילימומאב) בישראל.

התוויות התכשיר כפי שאושרו ע"י משה"ב:

Yervoy (ipilimumab) is indicated for the treatment of advanced (unresectable or metastatic) melanoma.

Yervoy in combination with Opdivo (nivolumab) is indicated for the treatment of patient with advanced (unresectable or metastatic) melanoma.

בפירוט שלהלן כלולים העדכונים המהותיים בלבד (טקסט שנוסף מסומן בצבע אדום ובקו תחתון וטקסט שהוסר מסומן בצבע אדום ~~ובקו אמצעי~~).
למידע מלא על התרופה יש לעיין בעלון לרופא כפי שאושר על ידי משרד הבריאות.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום בריסטול- מאיירס סקוויב (ישראל) בע"מ.

בכבוד רב,
מיכל ניר ורדימון
מנהלת רגולציה

**עדכונים מהותיים בעלון לרופא:**

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### 5.10 Other Immune-Mediated Adverse Reactions~~, Including Ocular Manifestations~~

***YERVOY as a Single Agent***

Permanently discontinue YERVOY for clinically significant or severe immune-mediated adverse reactions. Initiate systemic corticosteroids at a dose of 1 to 2 mg/kg/day prednisone or equivalent for severe immune-mediated adverse reactions.

Monitor patients for signs or symptoms of ocular toxicity, which may include blurred vision and reduced visual acuity. Immune-mediated ocular toxicity may be associated with retinal detachment or permanent vision loss. Administer corticosteroid eye drops to patients who develop uveitis, iritis, or episcleritis. Permanently discontinue YERVOY for immune-mediated ocular disease that is unresponsive to local immunosuppressive therapy. *[See Dosage and Administration (2.3).]* If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, which has been observed in patients receiving YERVOY and may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Fatal or serious graft-versus-host disease (GVHD) can occur in patients who receive a CTLA-4 receptor blocking antibody either before or after allogeneic hematopoietic stem cell transplantation (HSCT). Follow patients closely for evidence of GVHD and intervene promptly. *[See Adverse Reactions (6.2).]* Consider the benefit versus risks of treatment with a CTLA-4 receptor blocking antibody after allogeneic HSCT.

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## 6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling.

- Immune-mediated enterocolitis/colitis *[see Warnings and Precautions (5.1)]*.
- Immune-mediated hepatitis *[see Warnings and Precautions (5.2)]*.
- Immune-mediated dermatitis/skin adverse reactions *[see Warnings and Precautions (5.3)]*.
- Immune-mediated neuropathies *[see Warnings and Precautions (5.4)]*.
- Immune-mediated endocrinopathies *[see Warnings and Precautions (5.5)]*.
- *Immune-mediated pneumonitis [see Warnings and Precautions (5.6)]*.
- *Immune-mediated nephritis and renal dysfunction [see Warnings and Precautions (5.7)]*.

- *Immune-mediated encephalitis [see Warnings and Precautions (5.8)]*.
- *Infusion reactions [see Warnings and Precautions (5.9)]*.
- Other immune-mediated adverse reactions~~, including ocular manifestations~~ *[see Warnings and Precautions (5.10)]*.
- Embryo-fetal toxicity *[see Warnings and Precautions (5.11)]*.

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## 6.2 Postmarketing Experience

The following adverse reactions have been identified during post approval use of YERVOY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Immune system disorders:* graft-versus-host disease

*Skin and Subcutaneous Tissue Disorders:* Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)