הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך אישור העלון:08.2017

שם תכשיר באנגלית ומספר רישום Yervoy 147-62-33522-00

שם בעל הרישום BRISTOL-MYERS SQUIBB (ISRAEL)

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
5.6 Other Immune-Mediated Adverse Reactions, Including Ocular Manifestations The following clinically significant immune-mediated adverse reactions were seen in less than 1% of YERVOY-treated patients in Study 1: nephritis, pneumonitis, meningitis, pericarditis, uveitis, iritis, and hemolytic anemia. Across the clinical development program for YERVOY, the following likely immune-mediated adverse reactions were also reported with less than 1% incidence: myocarditis, angiopathy, temporal arteritis, vasculitis, polymyalgia rheumatica, conjunctivitis, blepharitis, episcleritis, scleritis, leukocytoclastic vasculitis, erythema multiforme, psoriasis, pancreatitis, arthritis, autoimmune thyroiditis, sarcoidosis, neurosensory hypoacusis, autoimmune central neuropathy (encephalitis), myositis, polymyositis, and ocular myositis.	**5.6 Other Immune-Mediated Adverse Reactions, Including Ocular Manifestations** Permanently discontinue YERVOY for clinically significant or severe immune-mediated adverse reactions. …	**WARNINGS AND PRECAUTIONS**

Permanently discontinue YERVOY for clinically significant or severe immune-mediated adverse reactions. … (Reference : to align with USPI Aug 2015)		
6.1 Clinical Trials Experience … **Adverse reactions in patients with advanced melanoma treated with ipilimumab 3 mg/kg (n= 767). Frequencies are based on pooled data from 9 clinical trials investigating the ipilimumab 3 mg/kg dose in melanoma.** Common**:** headache, weight decreased; Very common: fatigue, pyrexia, vomiting, nausea, decreased appetite (Reference : SmPc , March 2017)	**6.1 Clinical Trials Experience** …	**ADVERSE REACTIONS**