

Erbix 5mg/ml, Solution for Infusion
ארביטוקס 5 מ"ג/מ"ל, תמיסה לעירו
Cetuximab 5 mg/ml

רופא/ה, רוקח/ת וצוות רפואי נכבדים,

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר Erbix 5mg/ml עודכן.

ההתוויות המאושרות:

Erbix® is indicated for the treatment of patients with epidermal growth factor receptor (EGFR) - expressing, RAS wild-type metastatic colorectal cancer

- In combination with irinotecan-based chemotherapy
- In first-line in combination with FOLFOX
- as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan

Erbix is indicated for the treatment of patients with squamous cell cancer of the head and neck (SCCHN)

- in combination with radiation therapy for locally advanced disease
- in combination with platinum-based chemotherapy for recurrent and/or metastatic disease
- as a single agent after failure of platinum-based chemotherapy for recurrent and/or metastatic disease

השינויים בעלון לרופא הינם

בסעיף 4.4 – Special warnings and precautions for use

Respiratory disorders

Cases of interstitial lung disease (ILD), including fatal cases, have been reported, with the majority of patients from the Japanese population.

Confounding or contributing factors, such as concomitant chemotherapy known to be associated with ILD, and pre-existing pulmonary diseases were frequent in fatal cases. Such patients should be closely monitored. In the event of symptoms (such as dyspnoea, cough, fever) or radiographic findings suggestive of ILD, prompt diagnostic investigation should occur.

If interstitial lung disease is diagnosed, cetuximab must be discontinued and the patient be treated appropriately.



Undesirable effects – 4.8 סעיף

Respiratory, thoracic and mediastinal disorders

Uncommon: Pulmonary embolism, interstitial lung disease, which may be fatal (see section 4.4).

למידע המלא יש לעיין בעלון כפי שאושר על ידי משרד הבריאות.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום מרק סרונו בע"מ, רח' הקישון 18, יבנה 81220, טל' 09-9510737

בברכה,

אורית פוקס
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