

הודעה על החמרה (מידע בטיחות)

תאריך: 10/10/2011

שם תכשיר באנגלית: Tarceva® Tablets 100mg & 150mg

מספרי רישום: 133.43.31233.00 & 133.41.31234.00

שם בעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ

השינויים בעלון מסומנים ברקע צהוב

עלון לרופא

פרטים על השינויים המבוקשים		
טקסט חדש	טקסט נוכחי	פרק בעלון
Hypersensitivity to erlotinib or to any of the excipients.		4.3 CONTRAINDICATIONS
<p>Erlotinib is a substrate for the P-glycoprotein active substance transporter. Concomitant administration of inhibitors of Pgp, e.g. cyclosporine and verapamil, may lead to altered distribution and/or altered elimination of erlotinib. The consequences of this interaction for e.g. CNS toxicity has not been established. Caution should be exercised in such situations.</p> <p>Capecitabine may increase erlotinib concentrations. When erlotinib was given in combination with capecitabine, there was a statistically significant increase in erlotinib AUC and a borderline increase in C_{max} when compared with values observed in another study in which erlotinib was given as single agent. There were no significant effects of erlotinib on the pharmacokinetics of capecitabine.</p>		4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION