הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 12.11.17

שם התכשיר באנגלית ומספר הרישום 148 28 33391 00 Brinavess 20 mg/ml

שם בעל הרישום צמ"ל ביו-פארמה בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
Atrial flutter … In post-marketing experience very rare cases of atrial flutter with 1:1 atrioventricular conduction are observed.	Atrial flutter …	**Special warnings and precautions for use**
No formal interaction ….. BRINAVESS must not be administered in patients who received intravenous AADs (class I and III) within 4 hours prior to vernakalant (see section 4.3). Within the clinical development…	No formal interaction… Within the clinical development… …	**Interactios with other medicaments and other forms of interaction**
BRINAVESS has a minor to moderate influence on the ability to drive and use machines.		**Effects on ability to drive and use machines**
Atrial Flutter … However, in post-marketing experience very rare cases of atrial flutter with 1:1 atrioventricular conduction are observed. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il In addition, you may report by sending an e-mail message to safety@tzamal-medical.co.il or by visiting the "Contact Us" webpage at: http://www.tzamal-medical.co.il/69601.html or by phone: +972-73-7151107	Atrial Flutter … BRINAVESS did not develop 1:1 atrioventricular conduction.	**Adverse events**