

הודעה על החמרה (מידע בטיחות) בעלון לרופא

29.12.2016		תאריך אישור העלון :
142 95 32973 00/01/02 142 96 32974 00/01/02 145 63 33359 00/01/02	Pradaxa 75 mg Pradaxa 110 mg Pradaxa 150 mg	שם תכשיר ומספר רישום:
בורינגר אינגלהיים ישראל בע"מ, מדינת היהודים 89, ת.ד. 4124, הרצליה פיתוח 4676672		שם בעל רישום:

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
4.4 Special warnings and precautions for use	None	<p><u>Haemorrhagic risk</u></p> <p>...</p> <p>For situations of life-threatening or uncontrolled bleeding, when rapid reversal of the anticoagulation effect of dabigatran is required, the specific reversal agent (Praxbind, iduarcizumab) is available (see section 4.9).</p> <p>...</p> <p><u>Surgery and interventions</u></p> <p>...</p> <p><i>Emergency surgery or urgent procedures</i> Dabigatran etexilate should be temporarily discontinued. When rapid reversal of the anticoagulation effect is required the specific reversal agent (Praxbind, idarucizumab) to Pradaxa is available.</p> <p>Reversing dabigatran therapy exposes patients to the thrombotic risk of their underlying disease. Pradaxa treatment can be re-initiated 24 hours after administration of Praxbind (idarucizumab), if the patient is clinically stable and adequate haemostasis has been achieved.</p> <p><i>Subacute surgery/interventions</i> Dabigatran etexilate should be temporarily discontinued. A surgery / intervention should be delayed if possible until at least 12 hours after the last dose. If surgery cannot be delayed the risk of bleeding may be increased. This risk of bleeding should be weighed against the urgency of intervention (for cardioversion see section 4.2).</p> <p><i>Elective surgery</i> If possible, Pradaxa should be discontinued at least 24 hours before invasive or surgical procedures. In patients at higher risk of bleeding or in major surgery where complete haemostasis may be required consider stopping Pradaxa 2-4 days before</p>

surgery. Clearance of dabigatran in patients with renal insufficiency may take longer. This should be considered in advance of any procedures.		
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