

# הודעה על החמרה (מידע בטיחות) בעלון לצרכן (במתכונת לעלון

(רופא)

(מעודכן 05.2013)

תאריך 07.12.2015

שם תכשיר באנגלית ומספר הרישום

Actilyse 20 mg 136 78 31438  
Actilyse 50 mg 059 55 26312

שם בעל הרישום בורינגר אינגלהיים ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
Common: <b>Very common:</b> intracerebral haemorrhage represents the major adverse reaction in the treatment of acute ischaemic stroke (up to <del>10</del> <b>15</b> % of patients without any increase of overall mortality and without any relevant increase in overall mortality and severe disability combined, i.e. mRS of 5 and 6).	Common: intracerebral haemorrhage represents the major adverse reaction in the treatment of acute ischaemic stroke (up to <del>10</del> % of patients without any increase of overall mortality and without any relevant increase in overall mortality and severe disability combined, i.e. mRS of 5 and 6).	4.8 Undesirable effects
<del>Uncommon</del> <b>Common:</b> <del>Intra</del> cranial-Intracerebral haemorrhage (such as cerebral haemorrhage, cerebral haematoma, haemorrhagic stroke, haemorrhagic transformation of stroke, intracranial haematoma, subarachnoid haemorrhage) in the treatment of acute myocardial infarction and acute pulmonary embolism	<del>Uncommon:</del> intracranial haemorrhage (such as cerebral haemorrhage, cerebral haematoma, haemorrhagic stroke, haemorrhagic transformation of stroke, intracranial haematoma, subarachnoid haemorrhage) in the treatment of acute myocardial infarction and acute pulmonary embolism	4.8 Undesirable effects
<del>Rare</del> <b>Uncommon</b> Pulmonary haemorrhage (such as haemoptysis, hemothorax, respiratory tract haemorrhage)	<del>Rare:</del> bleeding in parenchymatous organs (such as hepatic haemorrhage, pulmonary haemorrhage)	4.8 Undesirable effects
<del>Very rare:</del> <b>Rare:</b> Ear haemorrhage	<del>Very rare:</del> Ear haemorrhage	4.8 Undesirable effects