

**Actilyse 50 mg**

אקטיליז 50 מ"ג

alteplase 50 mg/vial

**powder and solvent for solution for  
injection/infusion****Actilyse 20 mg**

אקטיליז 20 מ"ג

alteplase 20 mg/vial

**powder and solvent for solution for  
injection/infusion****הנדון: עדכון עלון לצרכן במתכונת עלון לרופא**

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת בורינגר אינגלהיים ישראל בע"מ מבקשת להודיעכם על עדכון בעלון לצרכן במתכונת עלון לרופא של התכשירים שבנדון.

ההתוויות הרשומות לתכשירים בישראל:

**Acute myocardial infarction:**

Actilyse is indicated for use in the management of acute myocardial infarction (AMI) in adults for the lysis of thrombi obstructing coronary arteries, the reduction of infarct size, improvement of ventricular function, the reduction of the incidence of congestive heart failure and the reduction of mortality associated with AMI.

Treatment should be initiated as soon as possible after the onset of AMI symptoms.

**Acute massive pulmonary embolism with hemodynamic deprivation:**

Actilyse is indicated in the management of acute massive pulmonary embolism (PE) in adults:

- for the lysis of acute pulmonary emboli, defined as obstruction of blood flow to a lobe or multiple segments of the lung, and
- for the lysis of pulmonary emboli accompanied by unstable hemodynamics e.g. failure to maintain blood pressure without supportive measures.

The diagnosis should be confirmed by objective means, such as pulmonary angiography or noninvasive procedures such as lung scanning.

**For fibrinolytic treatment of acute ischaemic stroke:**

Treatment must be started as early as possible within 4.5 hours after onset of stroke symptoms and after exclusion of intracranial haemorrhage by appropriate imaging techniques (e.g. cranial computerized tomography or other diagnostic imaging method sensitive for the presence of haemorrhage). The treatment effect is time-dependent; therefore earlier treatment increases the probability of a favourable outcome. This treatment is restricted to a prescription by a specialist in neurology.

השינויים המשמעותיים ביותר בעלון סומנו מטה.

**הסבר:**

טקסט עם קו תחתית מציין טקסט שהוסף לעלון.  
טקסט עם קו חוצה מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לצרכן במתכונת עלון לרופא המאושר.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות. כמו כן,  
ניתן לקבלו על-ידי פנייה לבעל הרישום:  
בורינגר אינגלהיים ישראל בע"מ, רח' מדינת היהודים 89 הרצליה פיתוח, ובטלפון 09-9730500.

ב ב ר כ ה,

בת-אל מלכה כהן

רוקחת ממונה

בורינגר אינגלהיים ישראל

**עדכונים מהותיים בעלון לרופא****בסעיף 4. CLINICAL PARTICULARS עודכן המידע הבא:****4.8 Undesirable effects**

[...]

**Reporting of suspected adverse reactions:**

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: <https://sideeffects.health.gov.il>

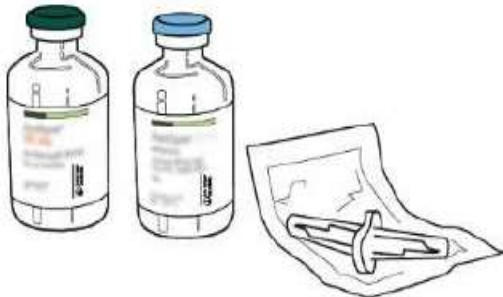
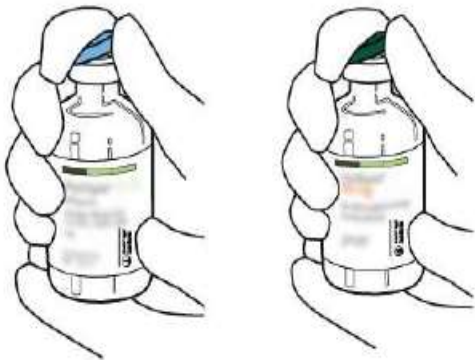
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

**בסעיף 6. PHARMACEUTICAL PARTICULARS עודכנו האיורים בהוראות הכנת התכשיר, וזאת בהתאם לעדכון התוויות פנימיות על גבי בקבוקון אבקת התכשיר Actilyse ועל גבי הממס (water for injections).**

## 6.6 Special precautions for disposal and other handling

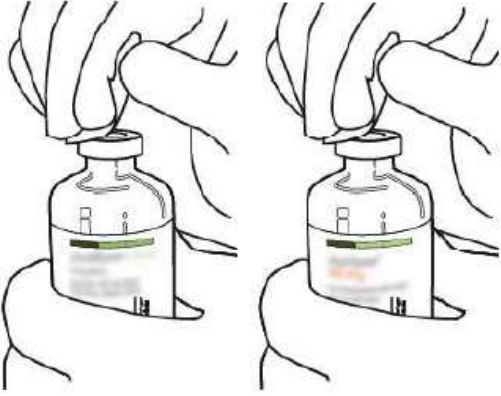
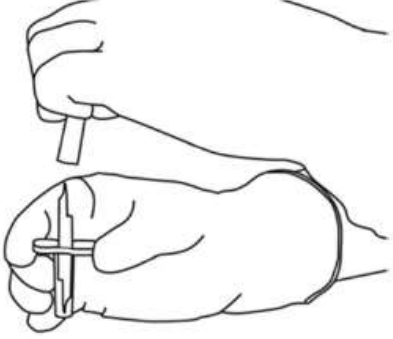

[...]

Instructions for reconstituting Actilyse

1	Reconstitute immediately before administration.	
2	Remove the protective cap on the two vials containing the sterile water and Actilyse dry substance by flipping them up with a thumb.	







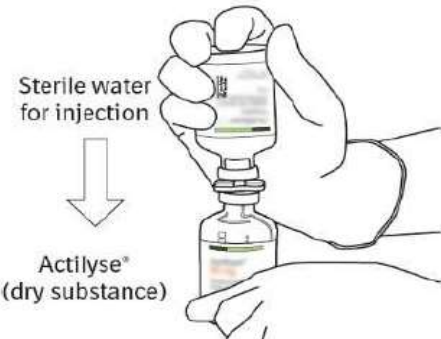

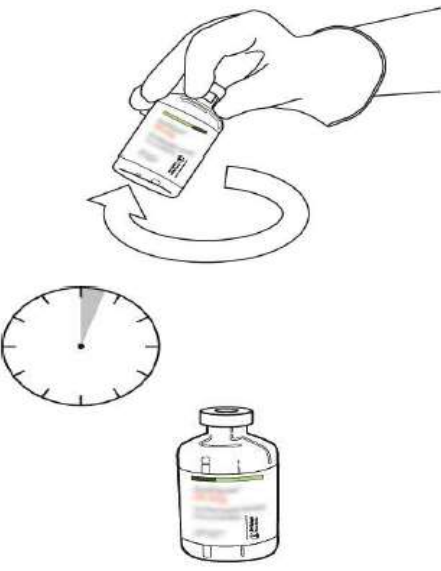
**Boehringer  
Ingelheim**

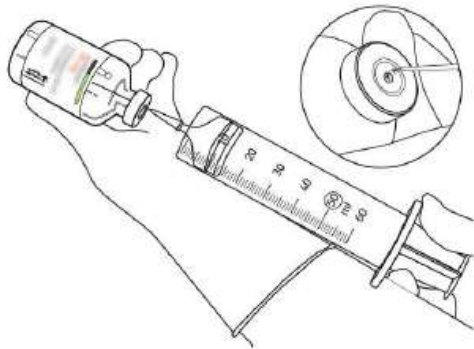
3	<p>Swab the rubber top of each vial with an alcohol wipe.</p>	
4	<p>Remove the transfer cannula from its cover. Do not disinfect or sterilize the transfer cannula; it is sterile. Take one cap off.</p>	
5	<p>Stand the sterile water vial upright on a stable surface. From directly above, puncture the rubber stopper vertically in the stopper center with the transfer cannula, by pressing gently but firmly, without twisting.</p>	 <p>Sterile water for injection</p>



**Boehringer  
Ingelheim**

6	<p>Hold the sterile water vial and the transfer cannula steady with one hand using the two side flaps.</p> <p>Remove the remaining cap on top of the transfer cannula.</p>	
7	<p>Hold the sterile water vial and the transfer cannula steady with one hand using the two side flaps.</p> <p>Hold the vial with Actilyse dry substance vertically above the transfer cannula and position the tip of the transfer cannula right in the center of the stopper.</p> <p>Push down the vial with the dry substance onto the transfer cannula from directly above, puncturing the rubber stopper vertically and gently but firmly without twisting.</p>	 <p>Actilyse® (dry substance)</p> <p>↓</p> <p>Sterile water for injection</p> 
8	<p>Invert the two vials and allow the water to drain completely into the dry substance.</p>	

		 <p>Sterile water for injection</p> <p>↓</p> <p>Actilyse® (dry substance)</p>
9	<p>Remove the empty water vial together with the transfer cannula. They can be disposed of.</p>	
10	<p>Take the vial with reconstituted Actilyse and swirl gently to dissolve any remaining powder, but do not shake, as this will produce foam.</p> <p>If there are bubbles, let the solution stand undisturbed for a few minutes to allow them to disappear.</p>	

11	The reconstituted solution consists of 1mg/mL alteplase. It should be clear and colourless to pale yellow and it should not contain any particles.	
12	Remove the amount required only by using a needle and a syringe. Do not use the puncture location from the transfer cannula to avoid leakage.	
13	Use immediately. Dispose of any unused solution.	