פברואר 2023

Actilyse 20 mg	Actilyse 50 mg
אקטיליז 20 מ"ג	**אקטיליז 50 מ"ג**
alteplase 20 mg/vial	**alteplase 50 mg/vial**
powder and solvent for solution for injection/infusion	**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 infraction (AMI) in adults for the lysis of thrombi obstructing coronary arteries, the reduction of infract 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:
Actylise 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.

Boehringer Ingelheim Israel LTD
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הסבר:
טקסט עם קו תחתי 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:

4.2 Posology and method of administration

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Adjunctive therapy:

The safety and efficacy of this regimen with concomitant administration of heparin ~~and~~ or platelet aggregation inhibitors such as acetylsalicylic acid within the first 24 hours of onset of the symptoms have not been sufficiently investigated. ~~Administration~~ Therefore, administration of intravenous heparin or platelet aggregation inhibitors such as acetylsalicylic acid ~~or intravenous heparin~~ should be avoided in the first 24 hours after treatment with Actilyse due to an increased haemorrhagic risk. If heparin is required for other indications (e.g. prevention of deep vein thrombosis) the dose should not exceed 10,000 IU per day, administered subcutaneously.

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4.4 Special warnings and precautions for use

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Haemorrhages

The most common complication encountered during Actilyse therapy is bleeding. The concomitant use of ~~heparin anticoagulation~~ other active substances affecting coagulation or platelet function may

contribute to bleeding. As fibrin is lysed during Actilyse therapy, bleeding from recent puncture sites may occur. Therefore, thrombolytic therapy requires careful attention to all possible bleeding sites (including those following catheter insertion, arterial and venous puncture cutdown and needle puncture). The use of rigid catheters, intramuscular injections and non-essential handling of the patient should be avoided during treatment with Actilyse.

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4.6 Fertility, pregnancy and lactation

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Breast-feeding

It is ~~not known if~~ unknown whether alteplase is excreted into human milk and there is insufficient information on the excretion of alteplase in animal milk.

Caution should be exercised when Actilyse is used for a nursing woman and a decision must be made whether breast-feeding should be discontinued for the first 24 hours after use of Actilyse

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5.2 Pharmacokinetic properties

Alteplase is cleared rapidly from the circulating blood and metabolised mainly by the liver (plasma clearance 550 - 680 ml/min.). Under physiological conditions, the major portion of alteplase in the circulation is inhibitor-bound. Hepatic clearance of alteplase is not hindered by the presence of other proteins including alteplase inhibitors. Complexes of alteplase and its inhibitor are eliminated as free alteplase. The relevant plasma half-life t1/2 alpha is 4-5 minutes. This means that after 20 minutes less than 10% of the initial value is present in the plasma. For the residual amount remaining in a deep compartment, a beta-half-life of about 40 minutes was measured.

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