דצמבר 2022

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 computerised
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
Medinat Ha-Yehudim St, 89, P.O. Box 4124, Hertzliya –Pituach, Israel 4676672
Phone +9729-9730515 Fax +9729-9730549

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.

העלונן המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.
כמו כן, ניתן לקבלם 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:

4.4 Special warnings and precautions for use

[…]

Hypersensitivity
Immune-mediated hypersensitivity reactions associated with the administration of Actilyse can be caused by the active substance alteplase, gentamicin (a trace residue from the manufacturing process), or any of the excipients, ~~or the stopper of the glass vial with Actilyse powder which contains natural rubber (a derivative of latex).~~ No sustained antibody formation to the recombinant human tissue-type plasminogen activator molecule has been observed after treatment. There is no systematic experience with re-administration of Actilyse.
There is also a risk of hypersensitivity reactions mediated through a non-immunological mechanism.
Angio-oedema represents the most common hypersensitivity reaction reported with Actilyse. This risk may be enhanced in the indication acute ischaemic stroke and/or by concomitant treatment with ACE inhibitors (see section 4.5). Patients treated for any authorised indication should be monitored for angio-oedema during and for up to 24h after infusion.
If a severe hypersensitivity reaction (e.g. angio-oedema) occurs, the infusion should be discontinued and appropriate treatment promptly initiated. This may include intubation.

[…]

4.8 Undesirable effects

[…]

Immune system disorders	
rare	hypersensitivity reactions (e.g. rash, urticaria, bronchospasm, angio-oedema, hypotension, shock*)*
very rare	serious anaphylaxis

[…]

* See sections 4.4 and 4.5

[…]

**For the full list of adverse reactions, please see the prescribing information.

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.
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) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

~~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.health.gov.il)~~

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