יולי 2019

רופא/ה יקר/ה,
רוקח/ת יקר/ה,

<u>הנדון: עדכון עלון של התכשיר Actilyse 20 mg and Actilyse 50 mg</u>
<u>(Alteplase)</u>

חברת בורינגר אינגלהיים ישראל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר בנדון.

ההתוויה הרשומה לתכשיר בישראל:

<u>Acute Myocardial Infarction</u>
In adults for the lysis of thrombi obstructing coronary arteries, the reduction of infarct size, the 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.

<u>Acute Massive Pulmonary embolism with hemodynamic deprivation.</u>
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.

<u>For fibrinolytic treatment of acute ischaemic stroke</u>
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.

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,

מירי חזן
רוקחת ממונה
בורינגר אינגלהיים ישראל

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

עדכונים בעלון רופא:

Hypersensitivity

[…]

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.

[…]

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